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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2026–8845; Amendment No. 71–58]

RIN 2120–AA66

Airspace Designations; Incorporation by Reference Amendment of FAA Order JO 7400.11M

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, administrative correction.

SUMMARY: This action administratively corrects identified final rules published by FAA in the **Federal Register** between May and September 2026 so that certain published airspace designation amendments are transferred to the most-current revision of FAA Order JO 7400.11, which is incorporated by reference.

DATES: Effective date 0901 UTC October 20, 2026. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the next annual revision of FAA Order JO 7400.11.

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

A copy of FAA Order JO 7400.11, Airspace Designations and Reporting Points, may be viewed online or downloaded at www.faa.gov/air_traffic/publications/, and subsequent amendments at www.faa.gov/air_traffic/publications/airspace_amendments/.

FOR FURTHER INFORMATION CONTACT: Sarah A. Combs, Airspace Regulation

Group, Operational Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it makes the necessary updates to publication of airspace designations in the **Federal Register** made pursuant to 14 CFR part 71 within the National Airspace System.

History

The most-current revision of FAA Order JO 7400.11, Airspace Designations and Reporting Points (which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points), is incorporated by reference annually in 14 CFR 71.1 as of September 15, and amendments to that revision of the Order are published as final rules throughout the following 12 months. Certain of these final rules are referred to as “effective date straddling amendments” because there is a mismatch between the effective date of the incorporated Order and the effective date of the amendment to the Order. These final rules are published in the **Federal Register** as amendments to the current revision of the Order, but contain effective dates that fall after the date when the next revision of the Order has been incorporated by reference and is effective (*i.e.*, they straddle the effective dates of the current and prospective Orders). This occurs because the effective date of airspace designations is typically delayed by approximately two months after publication of the final rule amendment to align with aeronautical charting cycles.

Incorporation by Reference

This action corrects the identified effective date straddling amendments by transferring the amendment to the currently incorporated revision of FAA Order JO 7400.11. These amendments will be manually integrated into a subsequent revision of FAA Order JO 7400.11.

For the availability of FAA Order JO 7400.11, see **ADDRESSES**.

The Rule

This action corrects certain final rules (the identified effective date straddling amendments) published under 14 CFR part 71 which are depicted on aeronautical charts.

Because these final rules were published while FAA Order JO 7400.11K was effective and incorporated by reference, but their effective dates fell while FAA Order JO 7400.11M was effective and incorporated by reference, these rules effectively crossed annual update cycles. As a result, these rules were not manually integrated into either revision of FAA Order JO 7400.11.

This action formally transfers these active amendments to FAA Order JO 7400.11M, Airspace Designations and Reporting Points, dated July 30, 2026, and effective September 15, 2026.

Accordingly, as this is an administrative correction to transfer the final rule amendments to the currently incorporated revision of FAA Order JO 7400.11, the FAA finds good cause under 5 U.S.C. 553(b)(B) that publishing this action for prior notice and public comment is unnecessary, and also finds good cause for making this amendment effective in fewer than 30 days.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT 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 amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Corrections

1. Correct FR Doc. No. 2026–09802, published on May 15, 2026, at 91 FR 27832 (Docket No. FAA–2025–1238; Airspace Docket No. 25–ASW–5), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

2. Correct FR Doc. No. 2026–11476, published on June 8, 2026, at 91 FR 34569 (Docket No. FAA–2026–3637; Airspace Docket No. 26–AGL–3), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

3. Correct FR Doc. No. 2026–11637, published on June 10, 2026, at 91 FR 35131 (Docket No. FAA–2026–3764; Airspace Docket No. 26–AGL–5), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

2. Correct FR Doc. No. 2026–11476, published on June 8, 2026, at 91 FR 34569 (Docket No. FAA–2026–3637; Airspace Docket No. 26–AGL–3), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30,

2026, and effective September 15, 2026”.

3. Correct FR Doc. No. 2026–11637, published on June 10, 2026, at 91 FR 35131 (Docket No. FAA–2026–3764; Airspace Docket No. 26–AGL–5), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

4. Correct FR Doc. No. 2026–11860, published on June 12, 2026, at 91 FR 35623 (Docket No. FAA–2026–3763; Airspace Docket No. 26–AGL–4), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

5. Correct FR Doc. No. 2026–11861, published on June 12, 2026, at 91 FR 35621 (Docket No. FAA–2026–3860; Airspace Docket No. 26–ASW–7), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

6. Correct FR Doc. No. 2026–11904, published on June 12, 2026, at 91 FR 35622 (Docket No. FAA–2026–3765; Airspace Docket No. 26–ASW–6), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

7. Correct FR Doc. No. 2026–12496, published on June 22, 2026, at 91 FR 36975 (Docket No. FAA–2026–4093; Airspace Docket No. 26–ASW–8), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and

replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

8. Correct FR Doc. No. 2026–12698, published on June 24, 2026, at 91 FR 37786 (Docket No. FAA–2026–4171; Airspace Docket No. 26–ASW–10), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

9. Correct FR Doc. No. 2026–12701, published on June 24, 2026, at 91 FR 37784 (Docket No. FAA–2026–4167; Airspace Docket No. 26–ASW–9), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

10. Correct FR Doc. No. 2026–13472, published on July 2, 2026, at 91 FR 40366 (Docket No. FAA–2026–3532; Airspace Docket No. 26–ASW–4), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

11. Correct FR Doc. No. 2026–13980, published on July 10, 2026, at 91 FR 42656 (Docket No. FAA–2026–3895; Airspace Docket No. 26–AGL–6), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and

replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

26. Correct FR Doc. No. 2026–16159, published on August 7, 2026, at 91 FR 51066 (Docket No. FAA–2026–6966; Airspace Docket No. 26–AGL–10), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

27. Correct FR Doc. No. 2026–16249, published on August 10, 2026, at 91 FR 51381 (Docket No. FAA–2026–0859; Airspace Docket No. 25–AAL–161), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

28. Correct FR Doc. No. 2026–16292, published on August 11, 2026, at 91 FR 51573 (Docket No. FAA–2026–6970; Airspace Docket No. 26–AGL–12), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

29. Correct FR Doc. No. 2026–16289, published on August 11, 2026, at 91 FR 51574 (Docket No. FAA–2026–6967; Airspace Docket No. 26–AGL–11), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

30. Correct FR Doc. No. 2026–16393, published on August 12, 2026, at 91 FR 52003 (Docket No. FAA–2026–6370; Airspace Docket No. 26–AEA–9), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

31. Correct FR Doc. No. 2026–18126, published on September 4, 2026, at 91 FR 56775 (Docket No. FAA–2026–7824; Airspace Docket No. 26–AEA–10), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

32. Correct FR Doc. No. 2026–18437, published on September 10, 2026, at 91 FR 57492 (Docket No. FAA–2026–3238; Airspace Docket No. 26–ASW–3), as follows:

a. Remove the text “FAA Order JO 7400.11K”, everywhere it appears, and replace it with the text “FAA Order JO 7400.11M”; and

b. Remove the text “dated August 4, 2025, and effective September 15, 2025”, everywhere it appears, and replace it with the text “dated July 30, 2026, and effective September 15, 2026”.

Issued in Washington, DC, on October 15, 2026.

Brian Eric Konie,

Acting Manager, Airspace Regulation Group.

[FR Doc. 2026–21422 Filed 10–19–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Parts 140, 141, 211, 213, 225, 226, 227, 243, 249, 273, and 700

[267A2100DD/AAKP3000000/
A0A501010.000000]

RIN 1076–AF81

Civil Penalties Inflation Adjustments; Annual Adjustments

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: This rule provides for annual adjustments to the level of civil monetary penalties contained in Bureau

of Indian Affairs (Bureau) regulations to account for inflation under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance.

DATES: This rule is effective on October 20, 2026.

ADDRESSES:

• *Federal eRulemaking Portal:* This rule may be found on the internet at <https://www.regulations.gov> by entering “RIN 1076–AF81” in the search box.

• *Alternative Format:* On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals can obtain this document in an alternate format, usable by people with disabilities, at the Office of the Assistant Secretary—Indian Affairs, Room 4660, 1849 C Street NW, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT:

Oliver Whaley, Director, Office of Regulatory Affairs and Collaborative Action (RACA), Office of the Assistant Secretary—Indian Affairs; Department of the Interior, RACA@bia.gov; telephone (202) 738–6065. 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.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Calculation of 2026 Annual Adjustments
- III. Procedural Requirements
 - A. Regulatory Planning and Review (Executive Order (E.O.s) 12866 and 14192)
 - B. Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)
 - C. Congressional Review Act (CRA)
 - D. Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*)
 - E. Takings (E.O. 12630)
 - F. Federalism (E.O. 13132)
 - G. Civil Justice Reform (E.O. 12988)
 - H. Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)
 - I. Paperwork Reduction Act
 - J. National Environmental Policy Act
 - K. Effects on the Energy Supply (E.O. 13211)
 - L. Clarity of This Regulation
 - M. Administrative Procedure Act

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (sec. 701 of Pub. L. 114–74) (“the Act”). The Act requires Federal agencies to adjust the level of civil monetary penalties with an initial “catch-up” adjustment through rulemaking and then make subsequent annual adjustments for inflation. The purpose of these adjustments is to

maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes.

The Office of Management and Budget (OMB) issued guidance for Federal agencies on calculating the catch-up adjustment. See February 24, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re: *Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (M–16–06). Under the guidance, the Department identified applicable civil monetary penalties and calculated the catch-up adjustment. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. The calculated catch-up adjustment is based on the percent change between the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October in the year of the previous adjustment (or in the year of establishment, if no adjustment has been made) and the October 2015 CPI-U.

The Bureau issued an interim final rule providing for calculated catch-up adjustments on June 30, 2016 (81 FR 42478), with an effective date of August 1, 2016, and requesting comments post-promulgation. The Bureau issued a final rule affirming the catch-up adjustments set forth in the interim final rule on December 2, 2016 (81 FR 86953). The Bureau then issued a final rule making the next scheduled annual inflation adjustment for 2017 on January 23, 2017 (82 FR 7649), for 2018 on February 6, 2018 (83 FR 5192), for 2019 on April 15, 2019 (84 FR 15098), for 2020 on February 19, 2020 (85 FR 9366), for 2021 on January 28, 2021 (86 FR 7344), for 2022 on March 9, 2022 (87 FR 13153), for 2023 on March 2, 2023 (88 FR 13018), for 2024 on March 13, 2024 (89 FR 18359), and for 2025 on June 5, 2025 (90 FR 23855).

II. Calculation of 2026 Annual Adjustments

OMB recently issued guidance to assist Federal agencies in implementing the annual adjustments required by the Act. See April 17, 2026, Memorandum for the Heads of Executive Departments and Agencies, from Russell T. Vought, Director, Office of Management and

Budget, re: *Cancellation of Penalty Inflation Adjustments for 2026, Regarding the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (M–26–11). The guidance informs agencies of the cancellation of the inflation adjustment for 2026 based on the lack of October 2025 CPI-U data from the Bureau of Labor Statistics due to the lapse in appropriations.

III. Procedural Requirements

A. Regulatory Planning and Review (E.O.s 12866 and 14192)

This rule has been determined to be not significant for purposes of E.O. 12866. This rule adjusts the level of existing civil monetary penalties and does not promulgate a new regulation defined in E.O. 14192.

In accordance with 5 U.S.C. 553(b)(4), a summary of this rule may be found at <https://www.regulations.gov> by searching for “RIN 1076–AF81.”

B. Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). A proposed inflation adjustment rule was not published in accordance with the Act. See Section III.M, “Administrative Procedure Act,” below.

C. Congressional Review Act (CRA)

This rule is not a major rule under 5 U.S.C. 804(2). This rule:

(a) Does not have an annual effect on the economy of \$100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does 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.

D. Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*)

This rule does not impose an unfunded mandate on State, local, or tribal governments, or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates

Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (E.O. 12630)

This rule does not affect a taking of private property or otherwise have taking implications under E.O. 12630. A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. A federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this 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.

H. Consultation With Indian Tribes (E.O. 13175 and Departmental 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. We have evaluated this rule under the Department's consultation policy and under the criteria in E.O. 13175 and have determined that it has no substantial direct effects on federally recognized Indian Tribes and that consultation under the Department's tribal consultation policy is not required.

I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

J. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969

(NEPA) is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of an administrative nature. For further information see 43 CFR 46.210(i). We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

L. Clarity of This Regulation

We are required by E.O. 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use clear language rather than jargon;
- (d) Be divided into short sections and sentences; and
- (e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **FOR FURTHER INFORMATION CONTACT** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you believe lists or tables would be useful, etc.

M. Administrative Procedure Act

The Act requires agencies to publish annual inflation adjustments by no later than January 15, of each year, notwithstanding section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). OMB has interpreted this direction to mean that the usual APA public procedure for rulemaking—which includes public notice of a proposed rule, an opportunity for public comment, and a delay in the effective date of a final rule—is not required when agencies issue regulations to implement the annual adjustments to civil penalties that the Act requires. Accordingly, we are issuing the annual adjustments as a final rule without prior notice or an opportunity for comment and with an effective date immediately upon publication in the **Federal Register**.

Section 553(b) of the APA provides that, when an agency for good cause finds that “notice and public procedure . . . are impracticable, unnecessary, or contrary to the public interest,” the agency may issue a rule without providing notice and an opportunity for prior public comment. Under section 553(b), the Bureau finds that there is good cause to promulgate this rule without first providing for public comment. It would not be possible to meet the deadlines imposed by the Act if we were to first publish a proposed rule, allow the public sufficient time to submit comments, analyze the comments, and publish a final rule. Also, the Bureau is promulgating this final rule to implement the statutory directive in the Act, which requires agencies to publish a final rule and to update the civil penalty amounts by applying a specified formula. The Bureau has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Accordingly, it would serve no purpose to provide an opportunity for public comment on this rule prior to promulgation. Thus, providing for notice and public comment is impracticable and unnecessary.

Furthermore, the Bureau finds under section 553(d)(3) of the APA that good cause exists to make this final rule effective immediately upon publication in the **Federal Register**. In the Act, Congress expressly required Federal agencies to publish annual inflation adjustments to civil penalties in the **Federal Register** by January 15 of each year, notwithstanding section 553 of the APA. Under the statutory framework and OMB guidance, the new penalty levels take effect immediately upon the effective date of the adjustment. The statutory deadline does not allow time to delay this rule’s effective date beyond publication.

List of Subjects

25 CFR Part 140

Business and industry, Indians, Penalties.

25 CFR Part 141

Business and industry, Credit, Indians—business and finance, Penalties.

25 CFR Part 211

Geothermal energy, Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR Part 213

Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR Part 225

Geothermal energy, Indians—lands, Mineral resources, Mines, Oil and gas exploration, Penalties, Reporting and recordkeeping requirements, Surety bonds.

25 CFR Part 226

Indians—lands.

25 CFR Part 227

Indians—lands, Mineral resources, Mines, Oil and gas exploration, Reporting and recordkeeping requirements.

25 CFR Part 243

Indians, Livestock.

25 CFR Part 249

Fishing, Indians.

25 CFR Part 273

Elementary and secondary education, Grant programs—Indians, Indians—education, Schools.

25 CFR Part 700

Indians, Indians—lands, Livestock.

William Henry Kirkland III,

Assistant Secretary—Indian Affairs.

[FR Doc. 2026–21474 Filed 10–19–26; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 260813–0186; RTID 0648–XG124]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries; Closure of the General Category October Through November Fishery for 2026

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the General category fishery for Atlantic bluefin tuna (BFT) for the remainder of the October through November time period. The General category may only retain, possess, or land large medium and giant

(i.e., measuring 73 inches (185 centimeters (cm) curved fork length (CFL) or greater) BFT when the fishery is open. This action also waives the previously scheduled restricted-fishing days (RFDs) for the remainder of the October through November time period. With the RFDs waived during the closure, fishermen aboard General category permitted vessels and HMS Charter/Headboat permitted vessels may tag and release BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs. On December 1, 2026, the fishery will reopen automatically.

DATES: Effective 11:30 p.m., local time, October 17, 2026, through November 30, 2026.

FOR FURTHER INFORMATION CONTACT:

Becky Curtis, becky.curtis@noaa.gov, or Larry Redd, Jr., larry.redd@noaa.gov, by email, or by phone at 301-427-8503.

SUPPLEMENTARY INFORMATION: Atlantic BFT fisheries are managed under the 2006 Consolidated Highly Migratory Species Fishery Management Plan (HMS FMP) and its amendments, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*). ATCA is the implementing statute for binding recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT). The HMS FMP and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27(a) divides the U.S. BFT quota, established by ICCAT and as implemented by the United States among the various domestic fishing categories, per the allocations established in the HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act at 16 U.S.C. 1854(g)(1)(D) to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

Under § 635.28(a)(1), NMFS files a closure action with the Office of the Federal Register for publication when a BFT quota (or subquota) is reached or is projected to be reached. Retaining, possessing, or landing BFT under that quota category is prohibited on or after the effective date and time of a closure action for that category until the opening of the relevant subsequent quota period or until such date as specified.

NMFS recently published a final rule, which among other things, increased the

BFT quota from 1,316.14 metric tons (mt) to 1,509.98 mt (not including the 62.5 mt ICCAT allocated to the U.S. to account for bycatch of BFT in pelagic longline fisheries in the vicinity of the management boundary and adjacent areas) (91 FR 53526, August 19, 2026). As described in § 635.27(a), the General category baseline quota is 815.4 mt. The General category baseline quota is suballocated to time periods. Relevant to this action, the baseline subquota for the October through November time period is 106 mt. On October 6, 2026, NMFS adjusted the October through November subquota to 192.9 mt (91 FR 64302, October 8, 2026).

Closure of the October Through November 2026 BFT General Category Fishery

Based on reported landings to date for the BFT General category October through November time period, NMFS has determined that the subquota for this time period is projected to be reached shortly. Therefore, retaining, possessing, or landing large medium or giant (i.e., measuring 73 inches (185 cm) CFL or greater) BFT by persons aboard vessels permitted in the Atlantic Tunas General category and HMS Charter/Headboat permitted vessels (while fishing commercially) must cease at 11:30 p.m. local time on October 17, 2026. The BFT General category will automatically reopen December 1, 2026, for the December 2026 time period. This action applies to Atlantic Tunas General category (commercial) permitted vessels and HMS Charter/Headboat permitted vessels with a commercial sale endorsement when fishing commercially for BFT and is taken consistent with the regulations at § 635.28(a)(1).

Waiver for Remaining October Through November RFDs

On May 31, 2024 (89 FR 47095), NMFS published a final rule, which, among other things, implemented RFDs every Tuesday, Friday, and Saturday from July 1 through November 30 of each year. Since the fishery will be closed for the remainder of the October through November time period, NMFS has decided to waive the previously scheduled RFDs for the remainder of that time period.

With the RFDs waived during a closure, consistent with § 635.23(a)(7) fishermen aboard General category permitted vessels and HMS Charter/Headboat permitted vessels may tag and release BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs described at § 635.26(a). All BFT that are released

must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the “Careful Catch and Release” brochure available at <https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure/>.

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Per § 635.5(b)(2)(i)(A), dealers are required to submit landing reports within 24 hours of receiving BFT. Late reporting by dealers compromises NMFS’ ability to timely implement actions such as quota and retention limit adjustments, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required per § 635.5(a)(4) to report their own catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing <https://hmspermits.noaa.gov>, using the HMS Catch Reporting app, or calling 888-872-8862 (Monday through Friday from 8 a.m. until 4:30 p.m. E.T.).

After the fishery reopens on December 1, depending on the level of fishing effort and catch rates of BFT at that time, and after consideration of all the criteria specified at § 635.27(a)(7), NMFS may determine that additional adjustments are necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may access <https://hmspermits.noaa.gov>, for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act (16 U.S.C. 1855(d)) and regulations at 50 CFR part 635, and this action is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice of, and an opportunity for public comment on this action because it is impracticable and contrary to the public interest for the following reasons. Specifically, the regulations implementing the HMS FMP and amendments provide for inseason

retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Providing for prior notice and an opportunity to comment is impracticable and contrary to the public interest as this fishery is currently underway and, based on the most recent landings information, the available time period subquota is projected to be reached shortly. Delaying this action could result in BFT

landings that exceed the adjusted October through November time period subquota, which may result in future potential quota reductions for other BFT categories or the 2027 General category quota, depending on the magnitude of a potential General category overharvest. Taking this action does not raise conservation and management concerns and would support effective management of the BFT fishery. NMFS notes that the public had an opportunity to comment on the underlying rulemakings that established the U.S.

BFT quota, and the inseason adjustment and closure criteria.

For all of the above reasons, the AA also finds that pursuant to 5 U.S.C. 553(d)(3), there is good cause to waive the 30-day delay in effective date.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: October 16, 2026.

Shannon Bettridge,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026-21450 Filed 10-16-26; 4:15 pm]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 91, No. 201

Tuesday, October 20, 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 AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS–2023–0016]

RIN 0579–AE83

Minimum Maturation Temperature for Beef and Ovine Meat From Regions Affected With Foot-and-Mouth Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations regarding the minimum maturation temperature for fresh (chilled or frozen) boneless beef and ovine meat from certain listed regions or countries affected with foot-and-mouth disease (FMD) from 4 °C to 2 °C. All other existing mitigations for the importation of beef from regions or countries affected with FMD would remain unchanged. This action is needed to align the regulations with the World Organization for Animal Health's standards for FMD minimum maturation temperatures, while continuing to protect the United States against the introduction of FMD.

DATES: We will consider all comments that we receive on or before December 21, 2026.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Enter APHIS–2023–0016 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2023–0016, Regulatory Analysis and Development, PPD, APHIS, 5601 Sunnyside Ave. #AP760, Beltsville, MD 20705.

Supporting documents and any comments we receive on this docket may be viewed at Regulations.gov or in

our reading room, which is in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Lisa M. Dixon, National Director, APHIS Veterinary Services, Strategy and Policy, Animal Product Imports and Exports, 5601 Sunnyside Avenue, Beltsville, MD 20705; (301) 851–3373; lisa.m.dixon@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including foot-and-mouth disease (FMD), African swine fever, classical swine fever, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine.

Under most circumstances, § 94.1 of the regulations prohibits the importation of live ruminants and swine and fresh (chilled or frozen) meat derived from ruminants and swine originating in, or transiting through, a region where FMD exists. Section 94.11 restricts the importation of ruminants and swine and their meat and certain other products from regions that are declared free of FMD but that nonetheless present a disease risk because of the regions' proximity to or trading relationships with regions affected with FMD. Regions that the Animal and Plant Health Inspection Service (APHIS) has declared free of FMD and regions declared free of FMD that are subject to the restrictions in § 94.11 are listed on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions>.

The regulations do allow for certain exceptions to the prohibitions contained in § 94.1. These exceptions include allowing the importation of fresh (chilled or frozen) beef from certain regions (Patagonia North A in Northern Argentina; Bahia, Distrito Federal,

Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Paraná, Rio Grande do Sul, Rio de Janeiro, Rondônia, São Paulo, Sergipe, and Tocantins in Brazil; Paraguay; and Uruguay), as well as ovine meat from Uruguay, subject to certain conditions. The conditions for the importation of boneless meat from these regions or countries affected with FMD are set out in § 94.29 of the regulations and require that:

- The meat is beef from animals that have been born, raised, and slaughtered in the exporting regions of Argentina or Brazil or in Paraguay; or beef or ovine meat from Uruguay derived from animals that have been born, raised, and slaughtered in Uruguay.

- Foot-and-mouth disease has not been diagnosed in the relevant exporting region within the previous 12 months.

- The meat comes from bovines or sheep that originated from premises where FMD has not been present during the lifetime of any bovines and sheep slaughtered for the export of beef and ovine meat to the United States.

- The meat comes from bovines or sheep that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.

- The meat comes from bovines or sheep that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no evidence found of vesicular disease.

- The meat consists only of bovine parts or ovine parts that are, by standard practice, part of the animal's carcass that is placed in a chiller for maturation after slaughter and before removal of any bone, blood clots, or lymphoid tissue. The bovine and ovine parts that may not be imported include all parts of the head, feet, hump, hooves, and internal organs.

- All bone and visually identifiable blood clots and lymphoid tissue have been removed from the meat; with the exception of ovine meat from Uruguay that meets certain listed conditions.

- The meat has not been in contact with meat from regions other than those listed as free of FMD.

- The meat came from carcasses that were allowed to mature at 40 to 50 °F (4 to 10 °C) for a minimum of 24 hours

after slaughter and that reached a pH below 6.0 in the loin muscle at the end of the maturation period. Measurements for pH must be taken at the middle of both *longissimus dorsi* muscles. Any carcass in which the pH does not reach less than 6.0 may be allowed to mature an additional 24 hours and be retested, and, if the carcass still has not reached a pH of less than 6.0 after 48 hours, the meat from the carcass may not be exported to the United States.

- An authorized veterinary official of the government of the exporting region certifies on the foreign meat inspection certificate that the above conditions have been met.

- The establishment in which the bovines and sheep are slaughtered allows periodic on-site evaluation and subsequent inspection of its facilities, records, and operations by an APHIS representative.

The World Organization for Animal Health (WOAH) code article 8.8.24, *Recommendations for importation of fresh meat of bovines from countries or zones infected with FMDV*, where an official control programme exists and article 8.8.26, *Recommendations for importation of fresh meat of sheep and goats from FMD infected countries or zones where an official control programme exists*¹ recommend that meat come from fresh deboned carcasses of bovine and sheep which, prior to deboning, have been submitted to maturation at a temperature greater than 2° C for a minimum period of 24 hours following slaughter and in which the pH value was less than 6.0 when tested in the middle of both the *longissimus dorsi* muscle as a mitigation for FMD.

As noted above, one of the requirements for the importation of fresh (chilled or frozen) boneless meat of bovine or ovine origin, from regions and countries in which FMD is known to exist, requires the meat to mature at a temperature between 4 to 10 °C for a minimum of 24 hours after slaughter. We are proposing to amend the regulations to align with WOAH standards, and decrease the minimum maturation temperature to 2 °C. All other existing requirements for the importation of such meat would remain unchanged and would continue to provide interlocking safeguards to mitigate for FMD.

Executive Orders 12866 and 14192 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the

purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. As a proposed rule, it also is not subject to Executive Order 14192.

In accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis, which is summarized below, regarding the economic effects of this proposed rule on small entities. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* website (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects.

The regulations in 9 CFR part 94 prohibit or restrict the importation of certain animals and animal products into the United States to prevent the introduction of various animal diseases, including foot-and-mouth disease (FMD). This proposed rule would lower the minimum maturation temperature for the importation of meat from certain regions, as part of an overall system approach to address FMD risk. The current minimum maturation temperature does not align with international standards. All other existing requirements for the importation of such meat would remain unchanged and would continue to provide interlocking safeguards to mitigate for FMD.

The entities that could potentially be impacted by this proposed rule are businesses within the beef and ovine meat agricultural sector, including beef cattle ranching and farming, cattle feedlots, sheep farming, animal slaughtering and processing, and meat and meat product importing and wholesaling. The majority of businesses in these industries are considered by the Small Business Administration to be small entities.

The United States has the largest fed-cattle industry in the world. The U.S. is also the world's largest producer of beef, primarily high-quality, grain-fed beef for domestic and export use. Nevertheless, the United States is a net importer of beef, primarily purchasing beef destined for processing, which tends to be lower-value, leaner, grass-fed beef. The U.S. beef industry, which is comprised of

over 600,000 farms and present in all 50 states, is roughly divided into two production sectors: Cow-calf operations and cattle feeding.

In 2024, U.S. beef consumption was about 29 billion pounds. The United States has a comparative advantage in producing higher-quality, grain-fed cattle, which results in higher-grading steaks, as well as lean beef trimmings and fat trimmings. Lean and fat trimmings are blended to make ground beef, which is by far the most consumed beef product in the U.S. By some estimates, between 50 percent and 55 percent of all beef in the U.S. is consumed in ground form. The corn-fed cattle in the domestic supply chain generate less lean beef trimmings than is necessary to satisfy the demand for ground beef. This results in a reliance on imported lean trimmings. Imports specifically of lean beef trimmings come largely from the countries affected by this proposed rule, as well as Australia and New Zealand. Lean beef imports also allow the U.S. beef industry to expand total beef production, add value by utilizing fat trimmings most efficiently, and export high-value beef products like primal cuts and steaks.

As this proposed rule makes no significant change that would affect the viability of exporting beef products from the affected countries, it is unlikely that there would be a significant increase in imports from this proposed rule. This proposed rule would not grant new market access for any countries or regions but would broaden the range of temperatures considered acceptable for the beef maturation process. Additionally, there is no evidence that the existing minimum maturation temperature is functioning as a barrier to trade.

This proposed rule would also marginally affect the requirements related to existing ovine meat imports from Uruguay, which currently represents less than one percent of annual U.S. lamb and mutton imports. The U.S. is a significant net importer of these products. Over the last five years, the U.S. has produced an average of 139 million pounds of lamb and mutton while importing an average of 335 million pounds. As with beef products, this proposed rule would not grant new market access for any producers of these products, nor is there any evidence that the existing minimum maturation temperature is functioning as a barrier to trade. As such, we do not expect any change in the trade of lamb and mutton from Uruguay as a result of this proposed rule.

While this proposed rule would have no direct impact on imports, we can

¹ To view these standards, go to https://www.woah.org/fileadmin/Home/eng/Health_standards/tahc/2024/en_chapitre_fmd.htm.

assume some hypothetical indirect impact to examine the welfare effects of such indirect impacts. To assess such a hypothetical change quantitatively, we used a range of 500 to 5,000 additional metric tons of imported beef products from the affected countries to compute impacts. In both scenarios, consumer welfare gains would outweigh producer welfare losses, with a positive net impact ranging from \$192,000 to \$1.92 million.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry

and poultry products, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 94 as follows:

PART 94—FOOT-AND-MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

- 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§ 94.29 [Amended]

- 2. Amend § 94.29 in paragraph (i), in the first sentence, by removing “40 to 50 °F (4 to 10 °C)” and adding “35.6 to 50 °F (2 to 10 °C)” in its place.

Done in Washington, DC, this 15th day of October 2026.

Kelly Moore,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2026–21433 Filed 10–19–26; 8:45 am]

BILLING CODE 3410–34–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 239, 249, 270, and 274

[Release No. 33–11444; 34–106534; IC–36351; File No. S7–2026–34]

RIN 3235–AN83

Interval Fund Modernization; Expansion of Multiple Share Class to Registered Closed-End Management Investment Companies and Business Development Companies

Correction

In proposed rules document 2026–20360 beginning on page 63388 in the issue of Monday, October 5, 2026, make the following correction:

1. On page 63388, in the first column, the **DATES** section is corrected to read as follows:

DATES: This release was published in the **Federal Register** on October 5, 2026. Comments should be received on or before December 4, 2026.

[FR Doc. C1–2026–20360 Filed 10–19–26; 8:45 am]

BILLING CODE 0099–10–D

Notices

Federal Register

Vol. 91, No. 201

Tuesday, October 20, 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 approval 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 19, 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.

Food Safety and Inspection Service

Title: Accreditation of Laboratories, Transactions, and Exemptions.

OMB Control Number: 0583–0082.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). These statutes mandate that FSIS protect the public by ensuring that meat, poultry, and egg products are safe, wholesome, and properly labeled. The Federal Meat Inspection Act (21 U.S.C. 642), the Poultry Products Inspection Act (21 U.S.C. 460 (b)) require certain parties to keep records that clearly show every business transaction involving animal carcasses and parts.

FSIS requires FSIS accredited non-Federal analytical laboratories to maintain certain information collection records. FSIS collects this information using FSIS forms 10,000–7, 10,120–1a, 10,120–1b, 10,120–1c, and 10,120–1d.

Need and Use of the Information: FSIS collects information to ensure that non-federal laboratories operate in accordance with FSIS regulations. In addition, FSIS also collects information to ensure that meat and poultry establishments exempted from Agency inspection do not commingle inspected and non-inspected meat and poultry products, and to ensure that retail operations determined to have violated the requirements associated with retail exemptions keep sales purchase and sales records to ensure future compliance. If the information was not collected or collected less frequently it would reduce the effectiveness of FSIS inspection programs.

Description of Respondents: Business or other for-profit.

Number of Respondents: 26,120.

Frequency of Responses:

Recordkeeping; Reporting: On occasion.

Total Burden Hours: 113,458.

Levi S. Harrell,

*Departmental Information Collection
Clearance Officer.*

[FR Doc. 2026–21409 Filed 10–19–26; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–241, C–533–953, C–201–871]

Certain Linear Hydraulic Cylinders and Parts Thereof From the People's Republic of China, India, and Mexico: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable October 20, 2026.

FOR FURTHER INFORMATION CONTACT: Natasia Byrd and Andrew Hart at (202) 482–1240 and (202) 482–1058, respectively (the People's Republic of China (China)), Ted Pearson and Ethan Lewis at (202) 482–2631 and (202) 482–4046, respectively (India), and Catherine Bonilla at (202) 482–7955 (Mexico), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On September 8, 2026, the U.S. Department of Commerce (Commerce) initiated countervailing duty (CVD) investigations of imports of certain linear hydraulic cylinders and parts thereof (hydraulic cylinders) from China, India, and Mexico.¹ Currently, the preliminary determinations are due no later than November 12, 2026.

Postponement of Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination in a CVD investigation until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner makes a timely request for a postponement; or

¹ See *Certain Linear Hydraulic Cylinders and Parts Thereof from the People's Republic of China, India, and Mexico: Initiation of Countervailing Duty Investigations*, 91 FR 58067 (September 14, 2026).

(B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On October 14, 2026, the petitioner² timely requested that Commerce postpone the preliminary CVD determinations to 130 days from the date of initiation, pursuant to 19 CFR 351.205(b) and (e).³ The petitioner stated a postponement is warranted to provide Commerce with additional time to review and analyze questionnaire responses, and issue supplemental questionnaires prior to making preliminary CVD determinations.⁴

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determinations, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determinations in the CVD investigations of hydraulic cylinders from China, India, and Mexico to no later than 130 days after the date on which these investigations were initiated, *i.e.*, January 19, 2027.⁵ Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations.

² The petitioner is the Hydraulic Cylinders Fair Trade Coalition, whose members are Aggressive Hydraulics Inc., Hol-Mac Corporation, Ligon Hydraulics, Prince Manufacturing Corporation, PTC, Alliance LLC, Rosenboom Machine & Tool Inc., Scot Industries Inc., Stillwell Inc., and Texas Hydraulics Inc.

³ See Petitioner's Letter, Petitioners' Request for Postponement of Preliminary CVD Determination," dated October 14, 2026, submitted on the record of each of these three investigations.

⁴ *Id.*

⁵ Commerce's practice dictates that where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. Therefore, the deadline for the preliminary determinations is January 19, 2027. See *Notice of Clarification: Application of "Next Business Day" Rule for Administrative Determination Deadlines Pursuant to Tariff Act of 1930, as Amended*, 70 FR 24533 (May 10, 2005).

Notification to Interested Parties

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: October 16, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–21452 Filed 10–19–26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–557–827, A–455–808, A–583–875, A–489–852]

Diocetyl Terephthalate From Malaysia, Poland, Taiwan, and the Republic of Türkiye: Antidumping Duty Orders; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Commerce (Commerce) published notice in the **Federal Register** of May 22, 2025, in which Commerce issued the antidumping duty (AD) orders on diocetyl terephthalate (DOTP) from Malaysia, Poland, Taiwan, and the Republic of Türkiye (Türkiye). The notice incorrectly stated the dates of the ending of provisional measures and the termination of suspension of liquidation due to the expiration of provisional measures.

FOR FURTHER INFORMATION CONTACT: Dennis McClure, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5973.

SUPPLEMENTARY INFORMATION:

Background

On May 22, 2025, Commerce published in the **Federal Register** the AD orders on DOTP from Malaysia, Poland, Taiwan, and Türkiye.¹ In the “Provisional Measures” section of that notice, we: (1) incorrectly stated that the six-month provisional measures period beginning on the date of the publication of the *Preliminary Determinations* ended on May 4, 2025; and (2) incorrectly stated that the termination of

¹ See *Diocetyl Terephthalate from Malaysia, Poland, Taiwan, and the Republic of Türkiye: Antidumping Duty Orders*, 90 FR 21897 (May 22, 2025).

suspension of liquidation due to the expiration of provisional measures began on May 5, 2025. The correct dates for the end of provisional measures and the termination of suspension of liquidation as a result of the expiration of provisional measures are May 3, 2025, and May 4, 2025, respectively.

Correction

In the **Federal Register** of May 22, 2025, in FR Doc 2025–09163, on page 21899, in the first column, correct the following sentences to read as follows: “Therefore, the six-month provisional measures period beginning on the date of publication of the *Preliminary Determinations* ended on May 3, 2025” and “. . . DOTP from Malaysia, Poland, Taiwan, and Türkiye entered, or withdrawn from warehouse, for consumption on or after May 4, 2025.”

Notification to Interested Parties

This notice is issued and published in accordance with section 736(a) of the Tariff Act of 1930, as amended, and 19 CFR 351.211(b).

Dated: October 15, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–21457 Filed 10–19–26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XG041]

Takes of Marine Mammals Incidental To Specified Activities; Taking Marine Mammals Incidental to the U.S. Navy's TRF Wharf Interface Repairs Project at U.S. Naval Submarine Base Kings Bay, Georgia

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from the U.S. Navy (Navy) for authorization to take marine mammals incidental to construction activities associated with Trident Refit Facility (TRF) wharf interface repairs project at Naval Submarine Base (NSB) Kings Bay, Georgia. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal

to issue an incidental harassment authorization (IHA) to take marine mammals incidental to the specified activities. NMFS is also requesting comments on a possible one-time, 1-year renewal that could be issued under certain circumstances and if all requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization.

DATES: Comments and information must be received no later than November 19, 2026.

ADDRESSES: Comments should be addressed to Permits and Conservation Division, Office of Protected Resources, NMFS, and should be submitted via email to ITP.Demarest@noaa.gov. 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.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Austin Demarest, 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). If such findings are made, 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).

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) 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 preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

Summary of Request

On March 12, 2026, NMFS received an email request from the Navy for an IHA to take marine mammals incidental to impact pile driving and vibratory pile removal on the East River at the naval submarine base NSB Kings Bay, Georgia. Following NMFS’ review of the application, the Navy submitted two revised versions on July 9, 2026, and on August 4, 2026. The application was deemed adequate and complete on August 17, 2026. The Navy’s request is

for take of Tamanend’s bottlenose dolphins (*Tursiops erebennus*) from the Southern Georgia Estuarine System (SGES) stock by Level B harassment only. Neither the Navy nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously issued 5-year regulations and an associated Letter of Authorization to the Navy for similar work at NSB Kings Bay (82 FR 26360, June 7, 2017; 82 FR 39568, August 21, 2017). The letter of authorization (LOA) expired on July 11, 2022. Information regarding the Navy’s activities under that previous LOA may be found on NMFS web page at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-us-navy-submarine-base-kings-bay-waterfront-construction-kings>.

Description of Proposed Activity

Overview

NSB Kings Bay on the East River in Georgia is the sole homeport on the east coast of the United States that was built to support the repair and maintenance of Trident Ship Submersible Ballistic and Nuclear-Powered Guided Missile Submarines. The waterfront infrastructure at the TRF wharf interface has severely degraded; the steel piles are corroded, and the concrete structures are spalling and delaminating. To maintain crucial submarine servicing capacity, the Navy proposes the TRF wharf interface repairs project to remove existing structures and replace them with new structures at the east and west wharfs. The east wharf consists of two concrete dolphin piers supported by steel piles, walkway ramps, mooring hardware, a fender system, a submerged caisson mooring pad, and the caisson gate mooring dock. The west wharf consists of three steel pile coffer cells, a concrete caisson, and hotel barge mooring system. In-water construction is planned to occur over a 1-year period, spanning 54 non-consecutive days.

Activities that have the potential to cause incidental take of marine mammals include vibratory pile removal of existing steel H-piles and impact driving new, permanent concrete piles. These activities may result in the incidental take of one stock of marine mammals, specifically the SGES stock of Tamanend’s bottlenose dolphins, by Level B harassment only. No Level A harassment, serious injury, or mortality is expected or proposed for authorization.

Dates and Duration

The proposed IHA would be valid for the statutory maximum of 1 year from the date of effectiveness. It will become effective upon written notification from the applicant to NMFS but not beginning later than 1 year from the date of issuance or extending beyond 2 years from the date of issuance. The specified activities are expected to occur over 54 non-consecutive days between January 2027 to December 2027, during daylight hours from 1 hour after sunrise to 1 hour before sunset. However, project delays may occur due to a number of factors, including project funding, permitting requirements, availability of equipment and/or materials, weather-

related delays, equipment maintenance and/or repair, transit to and from ports to survey locations, and other contingencies.

Specific Geographic Region

The Navy would replace infrastructure at NSB Kings Bay in the East River, situated in the eastern corner of Georgia, approximately 13 kilometers (km) north of the Florida-Georgia border, and approximately 14.8 km upstream from the Atlantic Ocean (figure 1). NSB Kings Bay encompasses a 16,000-acre area that provides berthing facilities and support services for naval submarines and other assets. The area is restricted to general public access and

includes the East River and adjacent waters of the Cumberland Sound between Marianna Creek to the north and Mill creek to the south. However, the ensouffied areas for the specified activities would not extend beyond the East River.

The environment of NSB Kings Bay is estuarine, receives saltwater inputs from tidal exchange with the ocean, and freshwater inputs from rivers, tributaries, and stormwater outfalls. The area has a large tidal range and contains strong currents which results in tidal mixing with water refreshed daily. See section 2 of the Navy's application for more detailed information.

BILLING CODE 3510-22-P

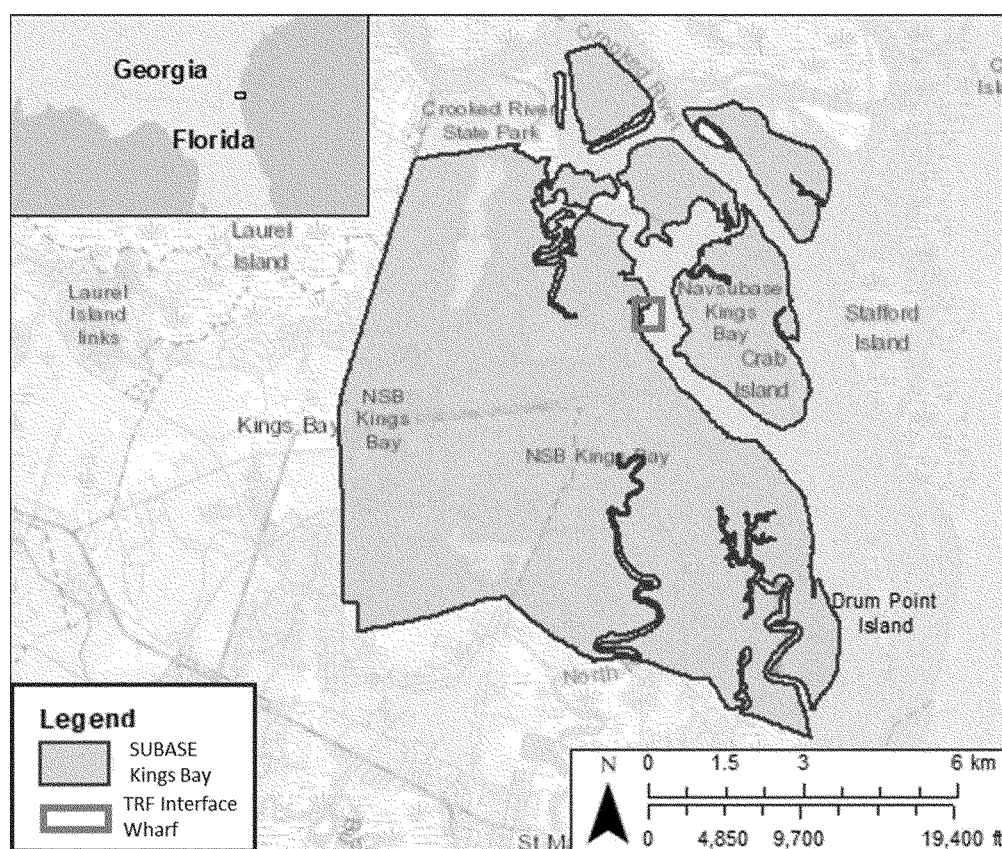


Figure 1 -- TRF Wharf Interface Repairs Project Geographic Location

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Detailed Description of the Specified Activity

Construction activities at NSB Kings Bay for the TRF wharf repairs project would occur at the east wharf interface, the east wharf interface dolphin piers, and the west wharf interface. Construction would involve the following repairs:

- Corrosion repair of concrete structures;

- Repair of deteriorated concrete piles;
- Creation of concrete fascia to protect existing coffer cells from further concrete corrosion;
- Demolition of the existing fender system and installation of a new fender system at the mooring dolphin piers, including the cleaning and installation of hardware, as needed;
- Removal of corroded steel H-piles along the east and west wharf; and

- Installation of new concrete piles for a new fender system along the east and west wharf.

For in-water construction, a total of 102 degraded 14-inch steel H-piles will be removed with a vibratory hammer, and then 112 20-inch square concrete replacement piles will be installed with an impact hammer (tables 1 and 2). Both pile removal and pile installation activities may occur on the same day but they will not occur simultaneously. If concrete piles are unable to reach

embedment depth with an impact hammer, these piles will be removed with direct pull methods, and then an auger will be used to drill through the limestone layers. Finally, these piles will be reinstalled with an impact hammer to reach embedment depth. Augering and other construction activities listed above, except vibratory pile removal and impact pile driving, are not expected to produce underwater sound at high enough levels or at a long enough duration to result in the incidental take of marine mammals. Therefore, these activities are not discussed further.

For the east wharf interface (excluding the dolphin pier), 33 14-inch steel H-piles from the existing fender mooring system will be removed with a vibratory hammer over 6 days. Following removal, 35 20-inch square

concrete piles for a new fender mooring system will be installed with an impact hammer over 11 days. Total in-water construction for the east wharf interface will occur over 17 non-consecutive days.

For the east wharf interface dolphin pier, six 14-inch steel H-Piles will be removed with a vibratory hammer over 2 days, and six 20-inch square concrete piles would be installed with an impact hammer over 2 days. To maintain the dolphin piers structural integrity during construction, activities will not be conducted in an entirely sequential manner. Instead, the Navy will remove four initial steel H-piles, install four replacement concrete piles, remove the last two steel H-piles, and install the last two concrete piles. Total in-water construction for the east wharf interface

dolphin pier will occur over a total of 4 non-consecutive days.

For the west wharf interface, 63 14-inch steel H-piles will be removed with a vibratory hammer for over 10 days, and 71 20-inch square concrete piles will be installed with an impact hammer for the new fender mooring system over 23 days. Total in-water construction for the west wharf interface will occur over a total of 33 non-consecutive days.

Incidental take of marine mammals by Level B behavioral harassment could occur from vibratory pile removal and impact pile installation.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting sections).

TABLE 1—TRF WHARF INTERFACE REPAIRS PROJECT VIBRATORY PILE EXTRACTION SUMMARY

Project component	Pile size and type	Piles/day	Time/pile (minutes)	Number of piles	Number of days
East Wharf	14-inch, Steel H	8	10	33	6
East Wharf Dolphin Pier		4	10	6	2
West Wharf		8	10	63	10
Totals				102	18

TABLE 2—TRF INTERFACE WHARF REPAIRS PROJECT IMPACT PILE INSTALLATION SUMMARY

Project component	Pile size and type	Piles/day	Strikes/pile	Number of piles	Number of days
East Wharf	20-inch, Square Concrete	4	500	35	11
East Wharf Dolphin Pier				6	2
West Wharf				71	23
Totals				112	36

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 3 lists the species and stock for which take is likely and proposed to be authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. 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 proposed to be 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. Atlantic Ocean and Gulf of America SARs. All values presented in table 3 are the most recent available at the time of publication (including from

the final 2024 SARs) and are available online at: <https://www.fisheries.noaa.gov/national/>

marine-mammal-protection/marine-mammal-stock-assessments.

TABLE 3—SPECIES, STOCKS, AND THE STATUS OF MARINE MAMMALS¹ WITH ESTIMATED TAKE FROM THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N) ²	Stock abundance (CV, Nmin, most recent abundance survey) ³	PBR	Annual M/SI ⁴
Order Odontoceti (toothed whales, dolphins, and porpoises)						
Family Delphinidae: Tamanend's Bottlenose Dolphin.	<i>Tursiops erebennus</i> ...	Southern Georgia Estuarine.	-, -, N	UNK (UNK, UNK, 2008–2009) ⁵ .	UND	0.1

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 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, vessel strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range.

⁵ The total number of common bottlenose dolphins residing within this stock is unknown because previous estimates are greater than 8 years old. Present data are insufficient to calculate a minimum population estimate for this stock. In addition, the previous abundance estimate covered approximately half of the entire range of the SGES stock and, therefore, is negatively biased.

As indicated above, only Tamanend's bottlenose dolphins from the SGES stock overlap temporally and spatially with the specified activity to the extent that take is likely (table 3). All species that could potentially occur in the proposed project areas are included table 4 of the IHA application. While table 4 of the Navy's application lists Tamanend's bottlenose dolphins from the Northern Georgia/Southern South Carolina Estuarine System (NGSCES), Central Georgia Estuarine System (CGES), and Jacksonville Estuarine System (JES) stocks as 'rare' in the project area, NMFS disagrees with this characterization because their spatial distribution does not overlap with the action area. Because their spatial and temporal ranges do not overlap with the specified activity, they are not expected to occur, take is not expected, and these stocks are not discussed further beyond the explanation provided here.

Specifically, the NGSCES stock's distribution ranges from the North Edisto River to the northern extent of Ossabaw Sound (approximately 64 nautical miles (nmi) north); the CGES stock's distribution ranges from Ossabaw Sound to the Altamaha Sound (approximately 38 nmi north); and the JES stock's distribution ranges from the Florida/Georgia border at Cumberland Sound to Jacksonville Beach, Florida (approximately 5.5 nmi south). Because the spatial distributions of these three

stocks do not overlap with the project area, and harassment zones are fully encompassed within the East River, take of these stocks is not expected or proposed to be authorized.

In addition, the West Indian manatee may be found in the East River in Georgia; however, West Indian manatees are managed by the U.S. Fish and Wildlife Service and are not considered further in this document.

Bottlenose dolphins frequently occur in estuarine and nearshore waters of southern Georgia, including the East River and the Cumberland Sound. Atlantic coastal and estuarine bottlenose dolphins were recategorized as Tamanend's bottlenose dolphins (*Tursiops erebennus*) by Costa *et al.* (2022). All bottlenose dolphins occurring within the project area are expected to belong to the SGES stock. The SGES stock geographic distribution is bounded by the Altamaha Sound to the north, the Florida/Georgia border in the Cumberland Sound to the south, and coastal waters within 1 km of shore (NMFS, 2023a). Because this stock has small geographic range, this area of southern Georgia is designated as a Small and Resident Population Biologically Important Area (BIA), encompassing approximately 410 km².

Speakman *et al.* (2023) conducted vessel-based dolphin photo-identification surveys from April 2010 through May 2021 in estuarine and

nearshore coastal waters (<5 km) from the Altamaha Sound to the Florida/Georgia border, encompassing the entirety of the SGES stock range. Their research confirmed high year-round site fidelity and localized residency within this estuarine system, supporting stock boundaries and presence. Across the 163 surveys, 768 distinctively marked photo-identified individual dolphins were documented (with a discovery curve that did not asymptote, indicating a larger population). Additionally, Speakman *et al.* (2023) performed a cluster analysis on individual dolphins (n=98) that were sighted at least 10 times, which identified 5 distinct social clusters. Across all five social clusters, the mean group size was 6.7 animals. While two social clusters have utilization distributions in the general surrounding region, fine-scale spatial mapping indicates that the core range of only one social cluster directly overlaps the project area (located within 2 nmi). The second social cluster's range lies farther away, outside the primary area of project effects. Consequently, project activities are expected to impact individuals from only this single overlapping social cluster.

The SGES stock dolphins utilize river estuaries, river channels, and tidal creeks between the Altamaha Sound and Cumberland Sound primarily for foraging, socializing, and transiting (Balmer *et al.*, 2013; NMFS, 2023a).

Local observations by subject matter experts (SMEs) at NSB Kings Bay confirm regular dolphin presence, with SMEs routinely observing two to three groups of dolphins daily in the project vicinity, where typical group sizes range from three to four individuals. Based on these local SME observations and known estuarine habitat use, individuals from this specific social cluster are expected to occur in the project area daily during the specified activities.

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 (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.*). 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; 2019). We note that the names of two hearing groups and the generalized hearing ranges of all marine mammal hearing groups have been recently updated (NMFS, 2024) as reflected below in table 4.

TABLE 4—MARINE MAMMAL HEARING GROUPS
[NMFS, 2024]

Hearing group	Generalized hearing range *
Low-frequency cetaceans (baleen whales)	7 Hz to 36 kHz.
High-frequency cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
Very High-frequency cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	200 Hz to 165 kHz.
Phocid pinnipeds (underwater) (true seals)	40 Hz to 90 kHz.
Otariid pinnipeds (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 approximately 65 dB threshold from composite audiogram, previous analysis in NMFS (2018), and/or data from Southall *et al.* (2007; 2019). Additionally, animals are able to detect very loud sounds above and below that “generalized” hearing range.

For more detail concerning these groups and associated frequency ranges, please see NMFS (2024) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation section to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Description of Sound Sources

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and

far (American National Standards Institute (ANSI), 1995). The sound level of an area is defined by the total acoustic energy being generated by known and unknown sources. These sources may include physical (e.g., waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (e.g., sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (e.g., vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise “ambient” or “background” sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor and is frequency dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10–20 dB from day to day (Richardson *et al.*, 1995). The result is that, depending on the source type and

its intensity, sound from the specified activities may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

In-water construction associated with the proposed project would include vibratory pile removal and impact pile driving. The sounds produced by these activities fall into one of two general sound types: impulsive and non-impulsive (defined below). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (e.g., Ward, 1997, in Southall *et al.*, 2007). Please see Southall *et al.* (2007) for an in-depth discussion of these concepts.

Impulsive sound sources (e.g., explosions, gunshots, sonic booms, impact pile driving) are brief (typically considered to be less than 1 second), broadband, atonal transients (ANSI, 1986; National Institute for Occupational Safety and Health (NIOSH), 1998; International Organization for Standardization (ISO) 2017; ANSI, 2005; NMFS, 2018) and occur either as isolated events or repeated in some succession. Impulsive sounds are all characterized by a relatively rapid rise from ambient pressure to a maximal pressure value

followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-impulsive sounds (*e.g.*, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems) can be broadband, narrowband or tonal, brief or prolonged (continuous or intermittent), and typically do not have the high peak sound pressure with rapid rise/decay time that impulsive sounds do (ANSI, 1995; NIOSH, 1998; NMFS, 2018). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to hearing (*e.g.*, Ward, 1997, in Southall *et al.*, 2007).

The Navy's TRF wharf interface repairs project would include the use of an impact hammer for pile installation and a vibratory hammer for pile removal. Impact hammers operate by repeatedly dropping a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers are used to remove piles by using vibration to break the sediment friction, which then allows a crane to vertically pull the piles out. Sounds produced by vibratory hammers are non-impulsive; compared to sounds produced by impact hammers, they have a slower rise time, reducing the probability and severity of injury, and the sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson *et al.*, 2005).

The likely or possible impacts of the Navy's proposed activities on the mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could result from the physical presence of the equipment and personnel; however, any impacts to marine mammals are expected to primarily be acoustic in nature.

Potential Effects of Underwater Sound on Marine Mammals

The introduction of anthropogenic noise into aquatic environment from pile driving and pile removal is the means by which marine mammals may be harassed from the Navy's specified activities. Anthropogenic sounds span a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life from none or minor to potentially severe

responses depending on received levels, duration of exposure, behavioral context, and various other factors. Broadly, underwater sound from active acoustic sources, such as those in the project, can potentially result in one or more of the following: temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.*, 1995; Gordon *et al.*, 2003; Nowacek *et al.*, 2007; Southall *et al.*, 2007; Götz *et al.*, 2009).

We describe the more severe effects of certain non-auditory physical or physiological effects only briefly as we do not expect that use of impact and vibratory pile driving hammers are reasonably likely to result in such effects (see below for further discussion). Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.*, 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.*, change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.*, 2006; Southall *et al.*, 2007; Zimmer and Tyack, 2007; Tal *et al.*, 2015). The specified activities considered here do not involve the use of devices such as explosives or mid-frequency tactical sonar that are associated with these types of effects.

In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.*, 2007; 2019). Exposure to anthropogenic noise has the potential to result in auditory threshold shifts (TS) and behavioral reactions (*e.g.*, avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). It can also lead to non-observable physiological responses, such as an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions, such as communication and predator and prey detection.

The degree of effect of an acoustic exposure on marine mammals is dependent on several factors, including, but not limited to, sound type (*e.g.*, impulsive vs. non-impulsive), signal characteristics, the species, age and sex

class (*e.g.*, adult male vs. mom with calf), duration of exposure, the distance between the noise source and the animal, received levels, behavioral state at time of exposure, and previous history with exposure (Wartzok *et al.*, 2004; Southall *et al.*, 2007). In general, sudden, high-intensity sounds can cause hearing loss as can longer exposures to lower-intensity sounds. Moreover, any temporary or permanent loss of hearing, if it occurs at all, will occur almost exclusively for noise within an animal's hearing range. We describe below the specific manifestations of acoustic effects that may occur based on the activities proposed by the Navy.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur in relation to distance from a source and assuming that the signal is within an animal's hearing range. First (at the greatest distance) is the area within which the acoustic signal would be audible (potentially perceived) to the animal but not strong enough to elicit any overt behavioral or physiological response. The next zone (closer to the receiving animal) corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. The third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory or other systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.*, when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the masking zone may be highly variable in size.

Below, we provide additional details regarding potential impacts on marine mammals and their habitat from noise in general, starting with hearing impairment, as well as from the specific activities the Navy plans to conduct, to the degree it is available.

Hearing Threshold Shift—NMFS defines a noise-induced TS as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018, 2024). The amount of TS is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018, 2024) there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.*, impulsive or non-impulsive), likelihood an individual would be exposed for a long enough

duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.*, spectral content), the hearing frequency range of the exposed species relative to the signal's frequency spectrum (*i.e.*, how animal uses sound within the frequency band of the signal; *e.g.*, Kastelein *et al.*, 2014), and the overlap between the animal and the source (*e.g.*, spatial, temporal, and spectral).

Auditory Injury (AUD INJ)—NMFS (2024) defines AUD INJ as damage to the inner ear that can result in destruction of tissue, such as the loss of cochlear neuron synapses or auditory neuropathy (Houser, 2021; Finneran, 2024). AUD INJ may or may not result in a permanent threshold shift (PTS). PTS is subsequently defined as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2024). PTS does not generally affect more than a limited frequency range, and an animal that has incurred PTS has some level of hearing loss at the relevant frequencies; typically, animals with PTS or other AUD INJ are not functionally deaf (Au and Hastings, 2008; Finneran, 2016). Available data from humans and other terrestrial mammals indicate that a 40-dB TS approximates AUD INJ onset (Ward *et al.*, 1958, 1959; Ward, 1960; Kryter *et al.*, 1966; Miller, 1974; Ahroon *et al.*, 1996; Henderson *et al.*, 2008). AUD INJ levels for marine mammals are estimates, as with the exception of a single study unintentionally inducing PTS in a harbor seal (*Phoca vitulina*) (Kastak *et al.*, 2008), there are no empirical data measuring AUD INJ in marine mammals largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing AUD INJ are not typically pursued or authorized (NMFS, 2024).

Temporary Threshold Shift (TTS)—TTS is a temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2024), and is not considered an AUD INJ. Based on data from marine mammal TTS measurements (Southall *et al.*, 2007; 2019), a TTS of 6 dB is considered the minimum TS clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Finneran *et al.*, 2000, 2002; Schlundt *et al.*, 2000). As described in Finneran (2015), marine mammal studies have shown the

amount of TTS increases with the 24-hour cumulative sound exposure level (SEL₂₄) in an accelerating fashion: at low exposures with lower SEL₂₄, the amount of TTS is typically small, and the growth curves have shallow slopes. At exposures with higher SEL₂₄, the growth curves become steeper and approach linear relationships with the sound exposure level (SEL).

Depending on the degree (elevation of threshold in dB), duration (*i.e.*, recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during a time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.*, 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019) for summaries). TTS is the mildest form of hearing impairment that can occur during exposure to sound. While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. For cetaceans, published data on the onset of TTS are limited to captive bottlenose dolphin (*Tursiops truncatus*), beluga whale (*Delphinapterus leucas*), harbor porpoise (*Phocoena phocoena*), and Yangtze finless porpoise (*Neophocoena asiaticaorientalis*) (Southall *et al.*, 2019). For pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals (*Mirounga angustirostris*), bearded seals (*Erignathus barbatus*), and California sea lions (*Zalophus californianus*) (Kastak *et al.*, 2007; Kastelein *et al.*, 2019b, 2019c, 2022a, 2022b; Reichmuth *et al.*, 2019; Sills *et*

al., 2020). TTS was not observed in spotted (*Phoca largha*) and ringed (*Pusa hispida*) seals exposed to single airgun impulse sounds at levels matching previous predictions of TTS onset (Reichmuth *et al.*, 2016). These studies examine hearing thresholds measured in marine mammals before and after exposure to intense or long-duration sound exposures. The difference between the pre-exposure and post-exposure thresholds can be used to determine the amount of TS at various post-exposure times.

The amount and onset of TTS depends on the exposure frequency. Sounds below the region of best sensitivity for a species or hearing group are less hazardous than those near the region of best sensitivity (Finneran and Schlundt, 2013). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity (*i.e.*, a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.*, 2019a, 2019c). Note that in general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). In addition, TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Mooney *et al.*, 2009; Finneran *et al.*, 2010; Kastelein *et al.*, 2014, 2015). This means that TTS predictions based on the total, SEL₂₄ will overestimate the amount of TTS from intermittent exposures, such as sonars and impulsive sources. Nachtigall *et al.* (2018) describe measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale (*Pseudorca crassidens*)) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Another study showed that echolocating animals (including odontocetes) might have anatomical specializations that might allow for conditioned hearing reduction and filtering of low-frequency ambient noise, including increased stiffness and control of middle ear structures and placement of inner ear structures (Ketten *et al.*, 2021). Data available on

noise-induced hearing loss for mysticetes are currently lacking (NMFS, 2024). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several dB above that inducing mild TTS (e.g., a 40-dB TS approximates PTS onset (Kryter *et al.*, 1966; Miller, 1974), while a 6-dB TS approximates TTS onset (Southall *et al.*, 2007; 2019). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulsive sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS SEL₂₄ thresholds are 15 to 20 dB higher than TTS SEL₂₄ sound exposure level thresholds (Southall *et al.*, 2007; 2019). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

Behavioral Effects—Exposure to noise also has the potential to behaviorally disturb marine mammals to a level that rises to the definition of harassment under the MMPA. Generally speaking, NMFS considers a behavioral disturbance that rises to the level of harassment under the MMPA a non-minor response—in other words, not every response qualifies as behavioral disturbance, and for responses that do, those of a higher level, or accrued across a longer duration, have the potential to affect foraging, reproduction, or survival. Behavioral disturbance may include a variety of effects, including subtle changes in behavior (e.g., minor or brief avoidance of an area or changes in vocalizations), more conspicuous changes in similar behavioral activities, and more sustained and/or potentially severe reactions, such as displacement from or abandonment of high-quality habitat. Behavioral responses may include changing durations of surfacing and dives, changing direction and/or speed; reducing/increasing vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); eliciting a visible startle response or aggressive behavior (such as tail/fin slapping or jaw clapping); and avoidance of areas where sound sources are located. In addition, pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006).

Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (e.g., species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (e.g., Richardson *et al.*, 1995; Wartzok *et al.*, 2004; Southall *et al.*, 2007; 2019; Weilgart, 2007; Archer *et al.*, 2010). Behavioral reactions can vary not only among individuals but also within an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.*, 2012), and can vary depending on characteristics associated with the sound source (e.g., whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. Please see appendices B and C of Southall *et al.* (2007) and Gomez *et al.* (2016) for reviews of studies involving marine mammal behavioral responses to sound.

Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.*, 2003). Animals are most likely to habituate to sounds that are predictable and unvarying. It is important to note that habituation is appropriately considered as a “progressive reduction in response to stimuli that are perceived as neither aversive nor beneficial,” rather than as, more generally, moderation in response to human disturbance (Bejder *et al.*, 2009). The opposite process is sensitization, when an unpleasant experience leads to subsequent responses, often in the form of avoidance, at a lower level of exposure.

As noted above, behavioral state may affect the type of response. For example, animals that are resting may show greater behavioral change in response to disturbing sound levels than animals that are highly motivated to remain in an area for feeding (Richardson *et al.*, 1995; Wartzok *et al.*, 2003; National Research Council (NRC), 2005). Controlled experiments with captive marine mammals have shown pronounced behavioral reactions, including avoidance of loud sound sources (Ridgway *et al.*, 1997). Observed responses of wild marine mammals to loud-pulsed sound sources (e.g., seismic airguns) have been varied but often consist of avoidance behavior or other

behavioral changes (Richardson *et al.*, 1995; Morton and Symonds, 2002; Nowacek *et al.*, 2007).

Available studies show wide variation in response to underwater sounds; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal (e.g., Erbe *et al.*, 2019). If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. If a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (e.g., Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005). However, there are broad categories of potential response, which we describe in greater detail here, that include alteration of dive behavior, alteration of foraging behavior, effects to breathing, interference with or alteration of vocalization, avoidance, and flight.

Avoidance and Displacement—Changes in dive behavior can vary widely and may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (e.g., Frankel and Clark, 2000; Costa *et al.*, 2003; Ng and Leung, 2003; Nowacek *et al.*, 2004; Goldbogen *et al.*, 2013a, 2013b; Blair *et al.*, 2015). Variations in dive behavior may reflect interruptions in biologically significant activities (e.g., foraging) or they may be of little biological significance. The impact of an alteration to dive behavior resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (e.g., bubble nets or sediment plumes), or changes in dive behavior. Acoustic and movement bio-logging tools also have been used in some cases to infer responses to anthropogenic noise. For example, Blair *et al.* (2015) reported significant effects on humpback whale (*Megaptera novaeangliae*) foraging behavior in Stellwagen Bank in response to ship noise including slower descent rates, and fewer side-rolling events per dive with increasing ship noise. In addition, Wisniewska *et al.* (2016) reported that tagged harbor porpoises demonstrated fewer prey capture attempts when encountering occasional high-noise

levels resulting from vessel noise as well as more vigorous fluking, interrupted foraging, and cessation of echolocation signals observed in response to some high-noise vessel passes. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (e.g., Croll *et al.*, 2001; Nowacek *et al.*, 2004; Madsen *et al.*, 2006; Yazvenko *et al.*, 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Respiration rates vary naturally with different behaviors and alterations to breathing rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Various studies have shown that respiration rates may either be unaffected or could increase, depending on the species and signal characteristics, again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure (e.g., Kastelein *et al.*, 2001; 2005; 2006; Gailey *et al.*, 2007). For example, harbor porpoise respiration rates increased in response to pile driving sounds at and above a received broadband SPL of 136 dB (zero-peak SPL: 151 dB (referenced to 1 micropascal (re 1 μ Pa); SEL of a single strike (SEL_{ss}): 127 dB re 1 μ Pa²-s) (Kastelein *et al.*, 2013).

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors and is one of the most obvious manifestations of disturbance in marine mammals (Richardson *et al.*, 1995). For example, gray whales (*Eschrichtius robustus*) are known to change direction—deflecting from customary migratory paths—in order to avoid noise from seismic surveys (Malme *et al.*, 1984). Harbor porpoises, Atlantic white-sided dolphins (*Lagenorhynchus actus*), and minke whales (*Balaenoptera acutorostrata*) have demonstrated avoidance in response to vessels during line transect surveys (Palka and Hammond, 2001). In addition, beluga

whales in the St. Lawrence Estuary in Canada have been reported to increase levels of avoidance with increased boat presence by way of increased dive durations and swim speeds, decreased surfacing intervals, and by bunching together into groups (Blane and Jaakson, 1994). Avoidance may be short-term, with animals returning to the area once the noise has ceased (e.g., Bowles *et al.*, 1994; Goold, 1996; Stone *et al.*, 2000; Morton and Symonds, 2002; Gailey *et al.*, 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (e.g., Blackwell *et al.*, 2004; Bejder *et al.*, 2006; Teilmann *et al.*, 2006).

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (e.g., directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996; Bowers *et al.*, 2018). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, marine mammal strandings (England *et al.*, 2001). However, it should be noted that response to a perceived predator does not necessarily invoke flight (Ford and Reeves, 2008), and whether individuals are solitary or in groups may influence the response.

Behavioral disturbance can also impact marine mammals in more subtle ways. Increased vigilance may result in costs related to diversion of focus and attention (i.e., when a response consists of increased vigilance, it may come at the cost of decreased attention to other critical behaviors such as foraging or resting). These effects have generally not been demonstrated for marine mammals, but studies involving fishes and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (e.g., Beauchamp and Livoreil, 1997; Fritz *et al.*, 2002; Purser and Radford, 2011). In addition, chronic disturbance can cause population declines through reduction of fitness (e.g., decline in body condition) and subsequent reduction in reproductive success, survival, or both (e.g., Harrington and Veitch, 1992; Daan *et al.*, 1996; Bradshaw *et al.*, 1998). However, Ridgway *et al.* (2006) reported

that increased vigilance in bottlenose dolphins exposed to sound over a 5-day period did not cause any sleep deprivation or stress effects.

Many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hour cycle). Disruption of such functions resulting from reactions to stressors such as sound exposure are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.*, 2007). Consequently, a behavioral response lasting less than 1 day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.*, 2007). Note that there is a difference between multi-day substantive (i.e., meaningful) behavioral reactions and multi-day anthropogenic activities. For example, just because an activity lasts for multiple days does not necessarily mean that individual animals are either exposed to activity-related stressors for multiple days or, further, exposed in a manner resulting in sustained multi-day substantive behavioral responses.

Physiological Stress Responses—An animal's perception of a threat may be sufficient to trigger stress responses consisting of some combination of behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses (e.g., Selye, 1950; Moberg, 2000). In many cases, an animal's first and sometimes most economical (in terms of energetic costs) response is behavioral avoidance of the potential stressor. Autonomic nervous system responses to stress typically involve changes in heart rate, blood pressure, and gastrointestinal activity. These responses have a relatively short duration and may or may not have a significant long-term effect on an animal's fitness.

Neuroendocrine stress responses often involve the hypothalamus-pituitary-adrenal system. Virtually all neuroendocrine functions that are affected by stress, including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction, altered metabolism, reduced immune competence, and behavioral disturbance (e.g., Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticoids are also equated with stress (Romano *et al.*, 2004).

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and

“distress” is the cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other functions. This state of distress will last until the animal replenishes its energetic reserves sufficient to restore normal function.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments and for both laboratory and free-ranging animals (e.g., Holberton *et al.*, 1996; Hood *et al.*, 1998; Jessop *et al.*, 2003; Krausman *et al.*, 2004; Lankford *et al.*, 2005; Ayres *et al.*, 2012; Yang *et al.*, 2021). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have also been reviewed (Fair and Becker, 2000; Romano *et al.*, 2002b) and, more rarely, studied in wild populations (e.g., Romano *et al.*, 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales (*Eubalaena glacialis*). In addition, Lemos *et al.* (2022) observed a correlation between higher levels of fecal glucocorticoid metabolite concentrations (indicative of a stress response) and vessel traffic in gray whales. Yang *et al.* (2021) studied behavioral and physiological responses in captive bottlenose dolphins exposed to playbacks of “pile-driving-like” impulsive sounds, finding significant changes in cortisol and other physiological indicators but only minor behavioral changes. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as “distress.” In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2005), however distress is an unlikely result of this project based on observations of marine mammals during previous, similar construction projects.

Norman (2011) reviewed environmental and anthropogenic stressors for Cook Inlet beluga whales. Lyamin *et al.* (2011) determined that the heart rate of a beluga whale increases in response to noise, depending on the

frequency and intensity. Acceleration of heart rate in the beluga whale is the first component of the “acoustic startle response.” Romano *et al.* (2004) demonstrated that captive beluga whales exposed to high-level impulsive sounds (i.e., seismic airgun and/or single pure tones up to 201 dB RMS) resembling sonar pings showed increased stress hormone levels of norepinephrine, epinephrine, and dopamine when TTS was reached. Thomas *et al.* (1990) exposed beluga whales to playbacks of an oil-drilling platform in operation (“Sedco 708,” 40 Hz–20 kHz; source level 153 dB). Ambient SPL at ambient conditions in the pool before playbacks was 106 dB and 134 to 137 dB RMS during playbacks at the monitoring hydrophone across the pool. All cell and platelet counts and 21 different blood chemicals, including epinephrine and norepinephrine, were within normal limits throughout baseline and playback periods, and stress response hormone levels did not increase immediately after playbacks. The difference between the Romano *et al.* (2004) and Thomas *et al.* (1990) studies could be the differences in the type of sound (seismic airgun and/or tone versus oil drilling), the intensity and duration of the sound, the individual’s response, and the surrounding circumstances of the individual’s environment. The sounds in the Thomas *et al.* (1990) study would be more similar to those anticipated by the Navy’s activities; therefore, no more than short-term, low-hormone stress responses, if any, of Tamanend’s bottlenose dolphins are expected as a result of exposure to noise from the Navy’s activities.

Vocalizations and Auditory Masking—Since many marine mammals rely on sound to find prey, moderate social interactions, and facilitate mating (Tyack, 2008), noise from anthropogenic sound sources can interfere with these functions, but only if the noise spectrum overlaps with the hearing sensitivity of the receiving marine mammal (Southall *et al.*, 2007; Clark *et al.*, 2009; Hatch *et al.*, 2012). Chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark *et al.*, 2009). Acoustic masking is when other noises such as from human sources interfere with an animal’s ability to detect, recognize, or discriminate between acoustic signals of interest (e.g., those used for intraspecific communication and social interactions, prey detection, predator avoidance, navigation) (Richardson *et al.*, 1995;

Erbe *et al.*, 2016). Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction. The ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (e.g., signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal’s hearing abilities (e.g., sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age or TTS hearing loss), and existing ambient noise and propagation conditions (Hotchkiss and Parks, 2013).

Marine mammals vocalize for different purposes and across multiple modes, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect increased vigilance or a startle response. For example, in the presence of potentially masking signals, humpback whales and killer whales (*Orcinus orca*) have been observed to increase the length of their songs (Miller *et al.*, 2000; Fristrup *et al.*, 2003) or vocalizations (Foote *et al.*, 2004), respectively, while North Atlantic right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.*, 2007). Fin whales (*Balaenoptera physalus*) have also been documented lowering the bandwidth, peak frequency, and center frequency of their vocalizations under increased levels of background noise from large vessels (Castellote *et al.*, 2012). Other alterations to communication signals have also been observed. For example, gray whales, in response to playback experiments exposing them to vessel noise, have been observed increasing their vocalization rate and producing louder signals at times of increased outboard engine noise (Dahlheim and Castellote, 2016). Alternatively, in some cases, animals may cease sound production during production of aversive signals (Bowles *et al.*, 1994, Wisniewska *et al.*, 2016).

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is human made, it may be considered

harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which occurs during the sound exposure. Because masking (without resulting in TS) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect (though not necessarily one that would be associated with harassment).

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (e.g., Clark *et al.*, 2009) and may result in energetic or other costs as animals change their vocalization behavior (e.g., Miller *et al.*, 2000; Foote *et al.*, 2004; Parks *et al.*, 2007; Di Iorio and Clark, 2010; Holt *et al.*, 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.*, 1995), through amplitude modulation of the signal, or through other compensatory behaviors, including modifications of the acoustic properties of the signal or the signaling behavior (Hotchkiss and Parks, 2013). Masking can be tested directly in captive species (e.g., Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (e.g., Branstetter *et al.*, 2013).

Masking occurs in the frequency band that the animals utilize, is more likely to occur in the presence of broadband, relatively continuous noise sources such as vibratory pile driving. Energy distribution of vibratory pile driving sounds spans a broad frequency spectrum, and is anticipated to be within the audible range of marine mammals present in the proposed action area. Since noises generated from the proposed construction activities are mostly concentrated at low frequencies (<2 kHz), these activities likely have less effect on mid-frequency echolocation sounds produced by odontocetes (toothed whales). However, lower frequency noises are more likely to

affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. Low-frequency noise may also affect communication signals when they occur near the frequency band for noise and thus reduce the communication space of animals (e.g., Clark *et al.*, 2009) and cause increased stress levels (e.g., Holt *et al.*, 2009). Unlike TS, masking, which can occur over large temporal and spatial scales, can potentially affect the species at population, community, or even ecosystem levels, in addition to individual levels. Masking affects both senders and receivers of the signals, and at higher levels for longer durations, could have long-term chronic effects on marine mammal species and populations. However, the noise generated by the Navy's proposed activities will only occur intermittently, across an estimated 54 days during the authorization period in a relatively small area focused around the proposed construction site. Thus, while the Navy's proposed activities may mask some acoustic signals that are relevant to the daily behavior of marine mammals, the short-term duration and limited areas affected make it very unlikely that the fitness of individual marine mammals would be impacted.

Potential Effects on Marine Mammal Habitat

The Navy's proposed activities would primarily have localized, temporary impacts on marine mammal habitat, including prey, by increasing in-water SPLs. Increased noise levels may affect acoustic habitat and adversely affect marine mammal prey in the vicinity of the project areas (see discussion below). Elevated levels of underwater noise would ensonify the project area where both fishes and mammals occur and could affect foraging success. Additionally, marine mammals may avoid the area during the proposed construction activities; however, displacement due to noise is expected to be temporary and is not expected to result in long-term effects on the individuals or populations.

The total area likely impacted by the Navy's activities is relatively small compared to the available habitat in the East River and the Cumberland Sound. Avoidance by potential prey (e.g., fish and benthic invertebrates) of the immediate area due to increased noise is possible. Any behavioral avoidance by fish or marine mammals of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity.

The proposed project will replace existing NSB Kings Bay infrastructure and remain within the same footprint. The nearshore estuarine habitat is in an area of high military vessel and submarine traffic. According to observations by NSB Kings Bay SMEs, dolphins generally transit through the project area but do not use the area within construction site footprint. Temporary, intermittent, and short-term habitat alteration may result from increased noise levels during the proposed construction activities. Effects on marine mammals will be limited to temporary displacement from pile installation and removal noise, and effects on prey species will be similarly limited in time and space.

Water quality—Temporary and localized reduction in water quality will occur as a result of in-water construction activities. Most of this effect would occur during the installation and removal of piles when bottom sediments are disturbed. The installation and removal of piles would disturb bottom sediments and may cause a temporary increase in suspended sediment in the project area. During pile extraction, sediment attached to the pile moves vertically through the water column until gravitational forces cause it to slough off under its own weight. The small resulting sediment plume is expected to settle out of the water column within a few hours. Studies of the effects of turbid water on fish (marine mammal prey) suggest that concentrations of suspended sediment can reach thousands of milligrams per liter before an acute toxic reaction is expected (Burton, 1993).

Effects to turbidity and sedimentation are expected to be short-term, minor, and localized. Since the tides are so strong in the area, following the completion of sediment-disturbing activities, suspended sediments in the water column should dissipate and quickly return to background levels in all construction scenarios. Turbidity within the water column has the potential to reduce the level of oxygen in the water and irritate the gills of prey fish species in the proposed project area. However, turbidity plumes associated with the project would be temporary and localized, and fish in the proposed project area would be able to move away from and avoid the areas where plumes may occur. Therefore, it is expected that the impacts on prey fish species from turbidity, and therefore on marine mammals, would be minimal and temporary. In general, the area likely impacted by the proposed construction activities is relatively small

compared to the available marine mammal habitat in the East River and Cumberland Sound.

Potential Effects on Prey—Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (e.g., crustaceans, cephalopods, fishes, zooplankton). Marine mammal prey varies by species, season, and location and, for some, is not well documented. Studies regarding the effects of noise on known marine mammal prey are described here.

Fishes utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (e.g., Zelick *et al.*, 1999; Fay, 2009). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.*, 2008). The potential effects of noise on fishes depends on the overlapping frequency range, distance from the sound source, water depth of exposure, and species-specific hearing sensitivity, anatomy, and physiology. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fish react to sounds that are especially strong and/or intermittent low-frequency sounds, and behavioral responses such as flight or avoidance are the most likely effects. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to noise depends on the physiological state of the fish, past exposures, motivation (e.g., feeding, spawning, migration), and other environmental factors. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fishes (e.g., Scholik and Yan, 2001, 2002; Popper and Hastings, 2009). Several studies have demonstrated that impulse sounds might affect the distribution and behavior of some fishes, potentially impacting foraging opportunities or increasing energetic costs (e.g., Fewtrell and McCauley, 2012; Pearson *et al.*, 1992; Skalski *et al.*, 1992; Santulli *et al.*, 1999; Paxton *et al.*, 2017). However, some studies have shown no or slight reaction to impulse sounds (e.g., Peña *et al.*, 2013; Wardle *et al.*, 2001; Jorgenson and Gyselman, 2009; Cott *et al.*, 2012). More commonly, though, the impacts of noise on fishes are temporary.

SPLs of sufficient strength have been known to cause injury to fishes and fish mortality (summarized in Popper *et al.*, 2014). However, in most fish species, hair cells in the ear continuously regenerate and loss of auditory function likely is restored when damaged cells are replaced with new cells. Halvorsen *et al.* (2012b) showed that a TTS of 4 to 6 dB was recoverable within 24 hours for one species. Impacts would be most severe when the individual fish is close to the source and when the duration of exposure is long. Injury caused by barotrauma can range from slight to severe and can cause death and is most likely for fish with swim bladders. Barotrauma injuries have been documented during controlled exposure to impact pile driving (Halvorsen *et al.*, 2012a; Casper *et al.*, 2013, 2017).

Fish populations in the proposed project area that serve as marine mammal prey could be temporarily affected by noise from impact pile installation and vibratory pile removal. The frequency range in which fishes generally perceive underwater sounds is 50 to 2,000 Hz, with peak sensitivities below 800 Hz (Popper and Hastings, 2009). Fish behavior or distribution may change, especially with strong and/or intermittent sounds that could harm fishes. High underwater SPLs have been documented to alter behavior, cause hearing loss, and injure or kill individual fish by causing serious internal injury (Hastings and Popper, 2005).

Zooplankton is a food source for several marine mammal species, as well as a food source for fish that are then preyed upon by marine mammals. Population effects on zooplankton could have indirect effects on marine mammals. Data are limited on the effects of underwater sound on zooplankton species, particularly sound from construction (Erbe *et al.*, 2019). Popper and Hastings (2009) reviewed information on the effects of human-generated sound and concluded that no substantive data are available on whether the sound levels from pile driving, seismic activity, or any human-made sound would have physiological effects on invertebrates. Any such effects would be limited to the area very near (1 to 5 m) the sound source and would result in no population effects because of the relatively small area affected at any one time and the reproductive strategy of most zooplankton species (short generation, high fecundity, and very high natural mortality). No adverse impact on zooplankton populations is expected to occur from the specified activity due, in part, to large reproductive capacities

and naturally high levels of predation and mortality of these populations. Any mortalities or impacts that might occur would be negligible.

The greatest potential impact to marine mammal prey during construction would occur during impact pile driving. In-water construction activities would only be initiated during daylight hours, allowing fish to forage and transit the project area undisturbed in the evening. Vibratory pile extraction may elicit behavioral reactions from fishes such as temporary avoidance of the area but is unlikely to cause injuries to fishes or have persistent effects on local fish populations. Construction would have minimal permanent and temporary impacts on benthic invertebrate species, a marine mammal prey source. In addition, it should be noted that the area in question is likely low-quality habitat since it is already highly developed and experiences a high level of anthropogenic noise from normal NSB Kings Bay operations and other vessel traffic.

Potential Effects on Foraging Habitat

The TRF wharf interface repairs project is not expected to result in any habitat-related effects that could cause significant or long-term negative consequences for individual marine mammals or their populations, since installation and removal of in-water piles would be temporary and intermittent. The total seafloor area affected by pile installation and removal is a very small area compared to the vast foraging area available to marine mammals outside this project area. NSB Kings Bay is a developed military installation that does not likely provide high-quality habitat for prey species. The area impacted by the proposed project is relatively small compared to the available habitat outside the area. The proposed project overlaps with small portion of the Small and Resident Population BIA designated for the SGES stock of Tamanend's bottlenose dolphins. While this area is biologically important to the stock, the maximum anticipated ensounded area is approximately 1 km², representing less than 1 percent of the 410 km² BIA. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. As described in the preceding, the potential for the Navy's construction to affect the availability of prey to marine mammals or to meaningfully impact the quality of physical or acoustic habitat is considered to be insignificant. Therefore, impacts of the project are not

likely to have adverse effects on marine mammal foraging habitat in the proposed project area.

In summary, given the project area is an industrialized Navy base, is a relatively small area being affected, as well as the temporary and mostly transitory nature of the proposed construction activities, any adverse effects from the Navy's activities on prey habitat or prey populations are expected to be minor and temporary. The most likely impact to fishes at the project site would be temporary avoidance of the area. Any behavioral avoidance by fish of the disturbed area would still leave significantly large areas of fish and marine mammal foraging habitat in the nearby vicinity. Thus, we preliminarily conclude that impacts of the specified activities are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization 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 would be by Level B harassment only, in the form behavioral reactions and/or TTS for individual marine mammals resulting from exposure to vibratory pile extraction and impact pile driving. Based on the nature of the activity and the anticipated effectiveness of the mitigation measures (*i.e.*, clearance and shutdown zones) discussed in detail below in the Proposed Mitigation section, Level A harassment is neither

anticipated nor proposed to be authorized.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed 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 proposed 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). Criteria for AUD INJ, and hearing group categories are available in NMFS' Updated Technical Guidance (NMFS, 2024) and are reflected below in the Level A harassment section.

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; 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 root-mean-squared sound pressure levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μ Pa)) for continuous (*e.g.*, vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (*e.g.*, seismic airguns) or intermittent (*e.g.*, scientific sonar) sources. Generally speaking, take estimates by Level B harassment are based on these behavioral harassment thresholds are expected to include any likely takes by 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.

Navy's proposed activity includes the use of continuous (vibratory pile removal) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μ Pa 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) (table 5). Navy's proposed activity includes the use of impulsive (impact driving) and non-impulsive (vibratory driving) 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 5—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 ($L_{p,0-pk}$) has a reference value of 1 μ Pa, and weighted cumulative sound exposure level ($L_{E,p}$) has a reference value of 1 μ Pa²s. 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 (TL) coefficient.

The source levels assumed for pile installation and removal are based on

reviews of measurements of the same or similar types and dimensions from similar coastal construction projects (table 6).

TABLE 6—THRESHOLDS IDENTIFYING THE ONSET OF AUDITORY INJURY

Pile size and type	Extraction and driving method	RMS SPL (dB re 1 μ Pa)	SEL (dB re 1 μ Pa ² -sec)	Peak SPL (dB re 1 μ Pa)	Reference
14-inch square steel H piles	Vibratory Extraction	150	NA	NA	Caltrans (2020).
20-inch square concrete piles	Impact Driving	177	164	189	Caltrans (2020).

Transmission Loss (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:

$$TL = B \times \log_{10}(R1/R2),$$

where:

TL = transmission loss in dB,
B = transmission loss coefficient,
R1 = the distance of the modeled SPL from the driven pile, and
R2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source depends on various factors, most notably the water bathymetry and the presence or absence of reflective or absorptive conditions, including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6-dB

reduction in sound level for each doubling of distance from the source ($20 \times \log[\text{range}]$). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source ($10 \times \log[\text{range}]$). A practical spreading value of 15 is often used in shallow-water coastal conditions, such as those found in the East River at NSB King Bay. In these environments, sound waves repeatedly reflect off the surface and bottom, reflecting an expected propagation environment between spherical and cylindrical spreading-loss conditions.

Site-specific TL data for the East River is not available; therefore, the default coefficient of 15 is used to calculate distances to the Level A harassment and Level B harassment thresholds. Assuming practicable spreading and other assumptions regarding the source characteristics and operational logistics (*e.g.*, source level, number of strikes per pile, number of piles per day), the Navy and NMFS calculated distances to the Level A harassment and Level B harassment thresholds and associated

ensonified areas. Because an ensonified area associated with Level A harassment is more technically challenging to predict given the accounting for a cumulative energy component that changes over time, to assist applicants in assessing the potential for Level A harassment without the need for complex modeling, NMFS developed an optional User Spreadsheet tool to accompany the 2024 Updated Technical Guidance (see <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance-other-acoustic-tools>). This relatively simple tool can be used to calculate a Level A harassment isopleth distance for use in conjunction with marine mammal density or occurrence data to predict the amount of take that may occur incidental to an activity. We note that, because of some of the assumptions in the methods underlying this spreadsheet tool, we anticipate that the resulting isopleths would typically be overestimates, which may lead to an overestimate of potential exposures from Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more

sophisticated modeling methods are not available or practical. For stationary sources such as vibratory pile removal and impact 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 7), and the resulting estimated isopleths (table 8), are reported below.

TABLE 7—NMFS USER SPREADSHEET INPUTS FOR THE NAVY'S TRF WHARF INTERFACE REPAIRS PROJECT

Pile size and material	Spreadsheet tab used	Source level (SPL)	Weighting factor adjustment	TL coefficient	Piles/day	Activity duration/pile (minutes), or (strikes/pile)	Distance of sound pressure level measurement (m)
Vibratory pile removal							
14-inch square steel H pile	A.1) Vibratory Pile Driving	150 dB RMS	2.5	15	^A 8 ^B 4	10	10
Impact pile driving							
20-inch inch square concrete piles.	E.1) Impact Pile Driving	177 dB RMS, 164 dB SEL, 189 dB PK.	2	15	4	500	10

^A 14-inch square steel H-piles at the east and west wharf will be removed at a maximum rate of 8 piles/day.

^B 14-inch square steel H-piles at the east wharf dolphin pier will be removed at a maximum rate of 4 piles/day to maintain the structural integrity of the existing dolphin pier.

TABLE 8—PROJECTED DISTANCES TO LEVEL A HARASSMENT AND LEVEL B HARASSMENT ISOPLETHS (m) BY MARINE MAMMAL HEARING GROUP FOR VIBRATORY REMOVAL AND IMPACT INSTALLATION

Project component	Pile size and material	Level A harassment distance (m)	Level B harassment distance (m)
		High frequency cetaceans	All marine mammals
Vibratory pile removal			
East and West Wharf	14-inch square steel H pile	^A 0.8	1,000
East Wharf Dolphin Pier		^B 0.5	
Impact pile driving			
East Wharf, West Wharf, and East Wharf Dolphin Pier.	20-inch inch square concrete piles	10.9	135.9

^A 14-inch square steel H-piles at the east and west wharf will be removed at a maximum rate of 8 piles/day.

^B 14-inch square steel H-piles at the east wharf dolphin pier will be removed at a maximum rate of 4 piles/day to maintain the structural integrity of the existing dolphin pier.

Marine Mammal Occurrence and Take Estimation

In this section, we provide information regarding the occurrence of marine mammals in the project area, including density and site-specific observational data, to inform the take calculations.

SMEs stationed at NSB Kings Bay informed the Navy that two to three groups of dolphins are observed each day year-round in the immediate vicinity of the TRF wharf interface repairs project. Group sizes during these observations typically range from three to four individuals per group. Similarly, Speakman *et al.* (2023) conducted vessel-based photo-identification surveys from Altamaha Sound to Cumberland Sound from 2010 through 2021. Based on cluster analysis, five distinct social clusters were identified within the SGES stock, with an overall mean group size of 6.7 dolphins across

all five clusters. The utilization distributions of clusters 1 and 2 were located closest to the project area, with mean group sizes of 5.1 and 5.5 individuals, respectively.

Although data from Speakman *et al.* (2023) indicate that local cluster group sizes range from 5.1 to 5.5 individuals, site-specific observational data from NSB Kings Bay indicates a typical maximum group size of four individuals. Considering the availability of site-specific observational data, the Navy proposed to estimate take assuming a group size of four dolphins and that two groups of dolphins could transit through the project area each day. NMFS evaluated the data from Speakman *et al.* (2023) along with the observational data from NSB Kings Bay and preliminarily concurs that the Navy's approach for estimating dolphin occurrence in the project area during the proposed activities is appropriate.

Take by Level B harassment was calculated using the following formula:

$$\text{Level B Harassment} = \text{Group Size (4)} \times \text{Groups/Day(2)} \times \text{Vibratory Pile Removal and Impact Pile Driving Days (54)}$$

Therefore, the total estimated take equates to 432 takes of Tamanend's bottlenose dolphins by Level B harassment.

Take by Level A harassment of marine mammals is not expected to occur during the specified activities. The largest modeled Level A harassment distance would occur during impact driving of four 20-inch square concrete piles (10.9 m for high-frequency cetaceans) (table 8). During construction, the Navy proposes to implement a 15-m clearance zone prior to the start of construction and 15-m shutdown zone for both vibratory pile removal and impact pile driving. It is highly unlikely that any Tamanend's

bottlenose dolphins would enter and remain within the relatively small Level A harassment distance long enough to incur an AUD INJ. Considering that the Navy did not request take by Level A

harassment and that it is highly unlikely an animal would remain within such a small area, NMFS does not expect take by Level A harassment to occur. Therefore, take by Level A harassment

of Tamanend's bottlenose dolphins is not expected and is not proposed for authorization.

TABLE 9—PROPOSED TAKE BY LEVEL B HARASSMENT FOR THE NAVY'S TRF WHARF INTERFACE REPAIRS PROJECT

Species	Stock	Level B harassment	Take as a percentage of the stock
Tamanend's Bottlenose Dolphin	Southern Georgia Estuarine	432	(^A)

^A A reliable abundance estimate is not available for this stock. However, across 163 surveys from 2010 to 2021 within the SGES stock range, 768 distinctively marked individual dolphins were photo-identified, representing 57 percent of all observed dolphins, and the growth curve did not asymptote (Speakman *et al.*, 2023).

Proposed 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 proposed mitigation requirements and has included them in the proposed IHA. These measures must be adhered to unless in the case of human safety concerns or pile refusal/instability.

Pre- and Post-Activity Monitoring

Prior to the start of daily in-water construction activities, or whenever a break in pile driving of 30 minutes or longer occurs, Protected Species Observers (PSOs) would observe for marine mammals at least 30 minutes (pre-clearance monitoring) through 30 minutes post-completion of pile removal or pile driving activities. Pre-start clearance monitoring must be conducted during periods of visibility sufficient for the PSOs to determine that the clearance zones indicated in table 10 are clear of marine mammals.

Soft Start Procedures for Impact Driving

Soft-start procedures 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. The Navy must use soft start techniques when impact pile driving. Soft start requires contractors to provide an initial set of three strikes at reduced energy, followed by a 30-second waiting period, then two subsequent reduced-energy strike sets.

A soft start must 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 applicable to vibratory pile removal.

Clearance and Shutdown Zones

For pile installation and removal activities, the Navy proposes to implement clearance and shutdown zones with radial distance of 15 m. The purpose of clearance and shutdown zones is to reduce the probability or scope of proximal acute impacts by taking steps in real time (*i.e.*, delay commencement of or stopping an activity) once a higher-risk scenario is identified. If a marine mammal is observed within a clearance or shutdown zone, or if a marine mammal enters or is observed within the clearance or shutdown zone while construction is ongoing, pile driving or pile removal must be delayed or halted. Operations may only resume once the animal is visually confirmed outside the zone or 15 minutes have passed without a re-detection.

Construction supervisors and crews, PSOs, and relevant Navy staff must avoid direct physical interaction with marine mammals during construction activities. If marine mammals come within 10 m of such activity, operations must cease, to avoid direct interaction. If an activity 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 shutdown zone indicated in table 10, or 15 minutes have passed without re-detection of the animal.

Finally, construction activities must be halted upon observation of a species for which incidental take is not authorized or a species for which incidental take has been authorized but the authorized number of takes has been met entering or within any clearance or shutdown zone. If a marine mammal

species not covered under the IHA enters a clearance or shutdown zone, all in-water activities would cease until the animal leaves the zone or has not been observed for at least 15 minutes. Pile driving may proceed if the unauthorized species is observed leaving the clearance and shutdown zone or if 15 minutes have passed since the last observation.

TABLE 10—PROPOSED CLEARANCE, SHUTDOWN AND LEVEL B HARASSMENT ZONES (m)

Pile size, type, and method	Clearance and shutdown zones (m)	Level B harassment zones (m)
	High Frequency Cetaceans	All Marine Mammals
14-inch, square steel H piles, vibratory removal	15	1000
20-inch square concrete piles, impact pile driving	15	140

Protected Species Observers

The number and placement of PSOs during all construction activities (described in the Proposed Monitoring and Reporting section) would be designed to ensure that the entire shutdown zone is visible. The Navy would employ a minimum of one PSO for impact pile driving and three PSOs would be on duty during all vibratory pile extraction activities for the TRF wharf interface repairs project.

Based on our evaluation of the applicant’s proposed measures, NMFS has preliminarily determined that the proposed 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.

Proposed 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 Navy in its adequate and complete application and are the result of subsequent coordination between NMFS and Navy. The Navy has agreed to the requirements. NMFS describes these below as requirements and has included them in the proposed IHA.

To ensure strict adherence to all terms and conditions of the proposed authorization and to guarantee that all monitoring and reporting requirements are diligently met, the Navy has established enhanced internal administrative and oversight protocols. A natural resources specialist at Naval Facilities Engineering Systems Command, Southeast (NAVFAC SE) will maintain and share a consolidated master list of all relevant points of contact, mitigating risks associated with

staff turnover and ensuring project notifications consistently reach the correct personnel. Prior to the start of construction, the assigned specialist will conduct a dedicated on-site meeting with project-level personnel to review specific permit requirements and establish a fixed, calendar-based schedule for the delivery of monitoring reports for review. Additionally, quarterly conferences between NAVFAC SE and Office of the Chief of Naval Operations staff will provide leadership with regular status updates and promptly address any perceived issues.

All PSOs must be NMFS-approved and have no other assigned tasks during monitoring periods. At least one PSO would have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued ITA.

During all vibratory pile removal and impact pile driving for the Navy’s TRF wharf interface repairs project, PSOs would monitor from various stations around the project area (see figures 8 through 18 in section 5.2 of the Navy’s application). PSOs would document marine mammal presence and behavior. During vibratory pile extraction, a minimum of three PSOs will monitor for marine mammals from stations shown in figures 10, 11, 14, 15, 18, and 19 of the Navy’s application. During impact pile driving, a minimum of one PSO will monitor for marine mammals from the pile driving location. For activities requiring multiple PSOs, if the stations presented in figures 8 through 19 of the Navy’s application do not provide adequate visual coverage of the required clearance, shutdown, and Level A and Level B harassment zones, the Navy will select alternative land-based monitoring stations that meet the criteria described above.

Monitoring would be conducted 30 minutes before, during, and 30 minutes after the specified activities. Additionally, 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 installing or removing 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.

The Navy would abide by all monitoring and reporting measures contained within the IHA, if issued, and their Protected Species Monitoring and Mitigation Plans (see NMFS' website at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>). NMFS describes these below as requirements and has included them in the proposed IHA.

Reporting

The Navy would be required to submit a draft report(s) on all construction activities and marine mammal monitoring results to NMFS within 90 days of the completion of monitoring, or 60 days prior to the requested issuance of any subsequent IHAs or similar activity at the same location, whichever comes first. The information required to be collected and reported to NMFS is included in the draft IHA available at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. In summary, the report would include, but not be limited to, information regarding activities that occurred, marine mammal sighting data, and whether mitigative actions were taken or could not be taken. The Navy would also be required to submit reports on any observed injured or dead marine mammals. If the death or injury was clearly caused by the specified activity, the Navy would immediately cease the specified activities until NMFS 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 the IHA. The Navy would not resume its activities until notified by NMFS.

Specific proposed mitigation, monitoring, and reporting requirements can be found in the draft IHAs found at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>.

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).

NMFS has identified key factors which may be employed to assess the level of analysis necessary to conclude whether potential impacts associated with a specified activity should be considered negligible. These include, but are not limited to, the type and magnitude of taking, the amount and importance of the available habitat for the species or stock that is affected, the duration of the anticipated effect to the species or stock, and the status of the species or stock. The potential effects of the specified activities on Tamanend's bottlenose dolphins are discussed below.

Pile driving and pile removal associated with the Navy's TRF wharf interface repairs project, as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in incidental take, in the form of Level B harassment only, from underwater sounds generated by pile driving and pile removal. Potential takes could occur if dolphins are present in zones ensounded above the threshold for Level B harassment identified above while activities are underway.

The Navy's proposed activities and associated impacts would occur within a limited, confined area of the stocks' range. In-water work would occur in the

vicinity of the NSB Kings Bay, and sound from the specified would be blocked by the shoreline of Crab Island and the East River. The intensity and duration of take by Level B harassment would be minimized through use of mitigation measures described herein. Further, the presence of dolphins in the area is expected to be limited, as the NSB Kings Bay is a military facility that experiences high levels of military vessel traffic. Dolphins that occur within the project area are expected to primarily transit through the East River, thereby reducing the potential for prolonged exposure or behavioral disturbance. In addition, NMFS does not anticipate that serious injury or mortality will occur as a result of the Navy's proposed activities given the nature of the activities, even in the absence of required mitigation.

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, will likely be limited to reactions such as avoidance, increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring) (*e.g.*, Ridgway *et al.*, 1997; Nowacek *et al.*, 2007; Thorson and Reyff, 2006; Kendall and Cornick, 2015; Goldbogen *et al.*, 2013b; Blair *et al.*, 2015; Wisniewska *et al.*, 2016; Piwetz *et al.*, 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, particularly as the project is located at naval base that experiences high levels of military vessel traffic. We expect that any avoidance of the project area by dolphins would be temporary in nature and that any marine mammals that avoid the project area during construction would not be permanently displaced. In-water construction would be limited to daylight hours from 1 hour after sunrise to 1 hour before sunset; thus, dolphins would be able to transit through or forage in the project area at night when construction activities are inactive. Therefore, short-term avoidance of the project area 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.

In addition to behavioral disturbances, exposure to elevated underwater sound levels may result in TTS or acoustic masking in some individuals present within the ensonified areas. Any TTS or masking experienced by dolphins would be low-level, short-term, and fully recoverable upon leaving the area. While minor acoustic masking or temporary reductions in hearing sensitivity could briefly interfere detections of acoustic cues, such as social communication whistles or echolocation clicks used for foraging, these effects would be localized and brief. Because pile driving is intermittent, acoustic masking and TTS will not disrupt communication or foraging to a degree that would cause chronic stress or affect individual health, survival, or reproduction.

As stated in the Monitoring and Reporting section, the Navy would implement shutdown zones. No take by Level A harassment is proposed for authorization and thus is not expected to adversely impact individual fitness, let alone annual rates of recruitment or survival for the affected species or stock.

This project is also not expected to have significant adverse effects on affected marine mammals' habitats. The project activities will not modify existing marine mammal habitat for a significant amount of time. The activities may cause some fish to leave the area of disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range. However, given the short duration of the activities and the relatively small area of the habitat that may be affected, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences.

Tamanend's bottlenose dolphins are common in the project area, with SMEs at NSB Kings Bay observing two to three groups of dolphins each day with group sizes ranging from three to four individuals per group. Speakman *et al.* (2023) conducted bottlenose dolphin surveys from the Altamaha Sound to the Cumberland Sound from 2010 through 2021, encompassing the range of the SGES stock. Analyses of these 163 surveys identified 5 distinct social clusters with minimal spatial overlap in habitat use. The core range of only one social cluster was located 2 nmi from the project site. Frequent sightings of bottlenose dolphins by NSB Kings Bay SMEs, combined with data from Speakman *et al.* (2023), indicate that project activities will primarily affect this single social cluster, with some

individuals likely transiting the project area repeatedly.

While the total number of takes proposed for authorization represents a notable proportion of SGES stock bottlenose dolphins, the majority of these exposures are expected to occur within this single social cluster whose core range is near the project site. Consequently, the requested take does not represent a broad impact to the entire stock, but rather repeated exposures of the same individuals. Although this social cluster may experience frequent exposures to elevated underwater sound levels, such intermittent disturbances are not expected to result in chronic stress or physical injury that would reduce the fitness, survival, or reproductive success of any individual. Animals from this social cluster are expected to temporarily avoid or quickly transit through the active project area during in-water construction, minimizing their exposure duration. Furthermore, the ensonified areas affect only a small portion of their overall habitat, leaving the majority of their core range undisturbed, and in-water construction will occur intermittently over 54 non-consecutive days during daylight hours rather than continuously. Because the anticipated impacts are localized to a small subset of the population and are not expected to affect the health or fitness of those individuals, the take proposed to be authorized will not affect annual rates of recruitment or survival for the SGES stock of Tamanend's bottlenose dolphins.

The Navy's TRF wharf interface repairs project is situated within the Small and Resident Population BIA for SGES stock of Tamanend's bottlenose dolphins. The area from the Altamaha Sound to the Cumberland Sound is designated as a Small and Resident Population BIA for SGES stock of Tamanend's bottlenose dolphins due to their limited geographic range. The ensonified areas from the specified activities are relatively small, representing less than 1 percent of the 410 km² area of the BIA. Therefore, ample high-quality habitat remains available to dolphins in the areas surrounding the East River to support individuals that may be temporarily displaced. Because the acoustic stressors occur intermittently and the physical footprint of the project is localized, the disturbance within the Small and Resident Population BIA will be short-term in duration and spatially confined. Consequently, the proposed action is not expected to diminish the value or functional role of the habitat within the BIA for the SGES stock of

Tamanend's bottlenose dolphins, and the overall effects on the designated BIA are expected to be de minimis.

In summary and as described above, the following factors primarily support our preliminary 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 Level A harassment, serious injury or mortality is anticipated or proposed to be authorized;
- Proposed take by Level B harassment does not represent a broad, stock-wide impact, but rather repeated, low-level exposures to a single social cluster whose core range is adjacent to the project site;
- Level B harassment would be primarily in the form of behavioral disturbance, resulting in avoidance of the project area around where impact pile driving and vibratory pile removal are occurring;
- Some temporary low-level TTS or acoustic masking may occur, briefly limiting the detection of acoustic cues (such as social communication whistles and echolocation) for short durations within a confined footprint, but these effects will be fully recoverable and will not affect individual fitness or survival;
- Behavioral disturbance will be temporary and localized; while dolphins may briefly avoid or quickly transit active work zones during pile driving, intermittent pauses during daylight hours and complete shutdown at night ensure continuous opportunities for undisturbed transiting and foraging;
- The ensonified areas, and project area in general, are small relative to the overall habitat of the SGES stock of Tamanend's bottlenose dolphins, and acoustic impacts within the Small and Resident Population BIA will be spatially minimal and short in duration, with construction occurring only over 54 non-consecutive days;
- Nearby areas of similar habitat value around the East River and the Cumberland Sound are available for marine mammals that may temporarily avoid the project area during construction activities; and
- Effects on marine mammal habitat and prey will be short-term and localized, causing no significant or long-term negative consequences to foraging success or population fitness.

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 proposed monitoring and mitigation measures, NMFS preliminarily finds

that the total marine mammal take from the proposed 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 (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.

The total abundance of the SGES stock of Tamanend's bottlenose dolphins is unknown in current NMFS Stock Assessment Reports because existing estimates are over 8 years old. However, empirical photo identification data provides the best available information regarding the minimum number of individuals residing within the geographic range of the SGES stock and establishes a baseline for the small numbers analysis. Across 163 surveys conducted between 2010 and 2021, Speakman *et al.* (2023) cataloged 768 distinctly marked individuals, accounting for 57 percent of the total individuals observed. Because the cumulative discovery curve did not reach an asymptote and the distinctively marked individuals represent only 57 percent of those observed, the total population size of the SGES stock is expected to exceed 768 individuals.

The best available science indicates that a much smaller number of unique individuals than the majority of the stock would be exposed repeatedly over the project duration. In-water construction for the proposed project will occur within a very small geographic area over 54 non-consecutive days. The geographic range for the SGES stock extends from the Altamaha Sound in the north to the Cumberland Sound in the south. This area is designated as a Small and Resident Population BIA for the SGES stock and encompasses an area over 410 km². The largest ensonified area from proposed project

activities is approximately 1 km², which represents less than 1 percent of the SGES stock's overall geographic range.

Speakman *et al.* (2023) demonstrated that individuals identified during the 2010 through 2023 surveys are partitioned into five distinct social clusters, each exhibiting strong site fidelity with minimal spatial overlap of core areas. The proposed projects action area is located approximately 2 nmi from the core distribution of only one of these five social structures (Speakman *et al.* 2023). The remaining four social clusters reside further from the project footprint and are not expected to occur in the action area or be incidentally taken during the specified activities. High site fidelity indicates that dolphins from cluster 2 may experience repeated daily exposures over the 54 days of in water work, resulting in 432 instances of take, while the actual number of unique individuals impacted remains small.

Because the specified activity is restricted to a small geographic area relative to the SGES stock's range, and because dolphins in this stock exhibit strong site fidelity within their core range, only one of five social clusters are likely to be within the project area. Considering these factors, it is reasonable to conclude that the number of unique individuals taken constitutes a small number of unique individuals taken constitutes a small number, representing less than one-third of the SGES stock population. Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily 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 ESA of 1973 (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 incidental take authorizations, NMFS consults internally whenever we propose to authorize take for ESA-listed species.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to the Navy for the TRF wharf interface repairs project in the East River at NSB Kings Bay, Georgia, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA).

- The request for renewal must include the following:

1. An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or

include changes so minor (*e.g.*, reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

2. A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

- Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: October 15, 2026.

Kimberly Damon-Randall,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

[FR Doc. 2026–21419 Filed 10–19–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Draft Revised Management Plans for the ACE Basin, Elkhorn Slough, and Weeks Bay National Estuarine Research Reserves; Notice of Proposed Boundary Changes

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Request for comments.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is soliciting comments from the public regarding a proposed revision of the management plans for the Ashepoo-Combahee-Edisto Basin (ACE Basin) National Estuarine Research Reserve in South Carolina, Elkhorn Slough National Estuarine Research Reserve in California, and Weeks Bay National Estuarine Research Reserve in Alabama. A management plan provides a framework to guide a reserve's programs, track progress toward meeting its goals, and identify potential opportunities or changes in direction. It is also used to guide programmatic evaluations of a reserve. Management plan revisions are required at least every five years. These draft revised

management plans are intended to replace the ACE Basin Research Reserve, Elkhorn Slough Research Reserve, and Weeks Bay Research Reserve management plans, which were approved in 2011, 2007, and 2017, respectively. NOAA is also considering requests to change the boundary of each reserve and is simultaneously soliciting comments from the public on the proposed boundary changes.

DATES: Comments must be received at the appropriate address (see **ADDRESSES**) on or before November 19, 2026.

ADDRESSES: The draft revised management plan for the ACE Basin Research Reserve can be downloaded or viewed at: dnr.sc.gov/marine/NERR. The draft revised management plan for the Elkhorn Slough Research Reserve can be downloaded or viewed at: elkhornslough.org/MP. The draft revised management plan for the Weeks Bay Research Reserve can be downloaded or viewed at: outdooralabama.com/WeeksBayNERRManagementPlan. Each plan is also available by sending a written request to the point of contact identified below (see **FOR FURTHER INFORMATION CONTACT**).

For the ACE Basin Research Reserve, you may submit comments by email to Elaine.Vaudreuil@noaa.gov. Include "Comments on draft ACE Basin Research Reserve Management Plan" in the subject line of the message. For the Elkhorn Slough Research Reserve, you may submit comments by email to Gemma.Waaland@noaa.gov. Include "Comments on draft Elkhorn Slough Research Reserve Management Plan" in the subject line of the message. For the Weeks Bay Research Reserve, you may submit comments by email to Matt.Chasse@noaa.gov. Include "Comments on draft Weeks Bay Research Reserve Management Plan" in the subject line of the message. The written comments NOAA receives are considered part of the public record, and the entirety of the comment, including the name of the commenter, email address, attachments, and other supporting materials, will be publicly accessible. Sensitive personally identifiable information, such as account numbers and Social Security numbers, should not be included with the comment. Comments that are not related to the management plan for the ACE Basin, Elkhorn Slough, or Weeks Bay Research Reserves, or that contain profanity, vulgarity, threats, or other inappropriate language, will not be considered.

FOR FURTHER INFORMATION CONTACT: ACE Basin Research Reserve: Elaine Vaudreuil, NOAA's Office for Coastal

Management, Elaine.Vaudreuil@noaa.gov, (202) 936–6008; Elkhorn Slough Research Reserve: Gemma Waaland, NOAA's Office for Coastal Management, gemma.waaland@noaa.gov, (707) 495–2623; Weeks Bay Research Reserve: Matt Chasse, NOAA's Office for Coastal Management, Matt.Chasse@noaa.gov, (240) 628–5417.

SUPPLEMENTARY INFORMATION: Pursuant to 15 CFR 921.33(c), the South Carolina Department of Natural Resources, the California Department of Fish and Wildlife, and the Alabama Department of Conservation and Natural Resources must revise the management plans for the ACE Basin Research Reserve, the Elkhorn Slough Research Reserve, and the Weeks Bay Research Reserve, respectively, at least every five years. If approved by NOAA, the revised management plan for the ACE Basin Research Reserve will replace the plan previously approved in 2011; the revised management plan for the Elkhorn Slough Research Reserve will replace the plan previously approved in 2007; and the revised management plan for the Weeks Bay Research Reserve will replace the plan previously approved in 2017.

Management plans outline a reserve's strategic goals and objectives; administrative structure; programs for conducting research and monitoring, education, and training; resource protection, restoration, and manipulation plans; public access and visitor use plans; consideration for future land acquisition; and facility development to support reserve operations.

In particular, this draft revised management plan for ACE Basin identifies four goals that the reserve will work toward over the next five years: Enable South Carolina's communities, residents, and visitors to protect coastal resources; advance knowledge about coastal and estuarine ecosystems through research and monitoring; apply science and stewardship to balance long-term protection of the ACE Basin's natural and cultural resources with enjoyment by current and future generations; and enhance the capacity of the reserve to contribute to the ACE Basin community, the South Carolina Department of Natural Resources, and the National Estuarine Research Reserve System through effective operations and communication. Since the last management plan, ACE Basin has engaged with new audiences and partners, filled some identified staffing needs, adapted training programs to include more virtual content, and successfully acquired lands that were

previously privately owned “in-holdings” adjacent to the reserve’s boundary. These parcels are now proposed for addition to the reserve’s boundary. The revised management plan, once approved, would serve as the guiding document for the ACE Basin Research Reserve for the next five years.

This draft revised management plan for Elkhorn Slough identifies five goals that the reserve will work toward over the next five years: Increase scientific understanding of estuarine ecosystems to inform conservation strategies; lead development and implementation of collaborative science-based conservation strategies to protect and restore native habitats in the Elkhorn Slough; increase awareness, understanding, and appreciation of the Elkhorn Slough; improve coastal decision-making through increased skills, knowledge, and access to key resources; and provide administrative leadership and resources necessary to improve the operations and infrastructure of the reserve. Since the last management plan, Elkhorn Slough has engaged with new audiences and partners; acquired 10 new parcels, nine of which were incorporated into the boundary in 2020 and one of which is now proposed for addition to their boundary; updated and added state-of-the-art interpretive exhibits to their visitor’s center and remodeled their outdoor teaching spaces; expanded their trail access; and continued to build upon their tidal wetland program through new marsh restoration projects. The revised management plan, once approved, would serve as the guiding document for the Elkhorn Slough Research Reserve for the next five years.

This draft revised management plan for Weeks Bay identifies four goals that the reserve will work toward over the next five years: Serve as a model to other coastal ecosystems through biologically diverse and resilient ecosystems within the Weeks Bay watershed; inform decisions affecting estuaries and coastal watersheds through an understanding of coastal ecosystems from science and monitoring; improve ecological appreciation to advance coastal literacy, conservation, and resiliency; and enhance the community sense of stewardship and appreciation of the local ecosystems. Since the last management plan, Weeks Bay has engaged with new audiences and partners, improved the resilience of their environmental monitoring capabilities, expanded training programs that incorporate reserve data, and successfully acquired lands adjacent to the reserve’s boundary.

Eleven parcels acquired by the Alabama Department of Conservation and Natural Resources, State Lands Division, and the State of Alabama Forever Wild Land Trust Program, as well as additional state-owned water bottoms, are now proposed for addition to the reserve’s boundary. The revised management plan, once approved, would serve as the guiding document for the Weeks Bay Research Reserve for the next five years.

NOAA’s Office for Coastal Management analyzes the environmental impacts of the proposed approval of this management plan, as well as the proposed boundary change, as required by the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321 *et seq.*

The public is invited to comment on the draft revised management plans. NOAA will take these comments into consideration when deciding whether to approve the revised management plans in whole or in part.

The public is also invited to comment on the proposal by the South Carolina Department of Natural Resources, as lead agency for managing the ACE Basin Research Reserve, to incorporate 12 state-owned parcels acquired since 2011 into the reserve’s approved boundary, as described in the draft management plan; the proposal by the California Department of Fish and Wildlife, as lead agency for managing the Elkhorn Slough Research Reserve, to incorporate one state-owned parcel acquired since 2020 into the reserve’s approved boundary, as described in the draft management plan; and the proposal by the Alabama Department of Conservation and Natural Resources, as lead agency for managing the Weeks Bay Research Reserve, to incorporate 11 state-owned parcels acquired since 2017 and additional state-owned water bottoms into the reserve’s approved boundary, as described in the draft management plan. Pursuant to 15 CFR 921.33(a), NOAA may require public notice, including notice in the **Federal Register** and an opportunity for public comment, before approving a boundary change. NOAA will take public comments into consideration when deciding whether to approve this proposed boundary change in whole or in part.

Authority: 16 U.S.C. 1451 *et seq.*; 15 CFR 921.33.

Keelin S. Kuipers,

Acting Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2026–21418 Filed 10–19–26; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2026–OS–2278]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the OUSD(A&S), DoD (referred to herein as “the Department”, “Department of War” or “DoW”) announces proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency’s 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 through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by December 21, 2026.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Department of War, Office of the Director of Administration and Management, Oversight and Compliance Directorate, Regulatory Division, 4800 Mark Center Drive, Mailbox #24, Suite 05F16, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and

associated collection of instruments, please write to Defense Security Cooperation Agency, 2800 War Pentagon, Washington, DC 20301, Mr. Jeffrey Troch or call 223-758-3336.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Security Assistance Network; OMB Control Number 0704-0555.

Needs and Uses: The Security Assistance Network (SAN) is a web-based database used to exchange Security Cooperation training information between overseas Security Cooperation Offices, Geographical Combatant Commands, Military Departments, Defense Security Cooperation Agency, DoW Schoolhouses, Regional Centers, and International Host Nation Organizations. The Security Cooperation Training Management System (SC-TMS) is a tool used by the Security Cooperation community to manage International Military Student training data.

Affected Public: Individuals or households.

Annual Burden Hours: 10,995.

Number of Respondents: 43,980.

Responses per Respondent: 1.

Annual Responses: 43,980.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

The International Military Student Information (IMSI) that is collected on the SAN is used by the International Military Student Officer (IMSO) assigned to each training installation to prepare for the arrival and stay in the U.S. of the international training student. The collection of this information, in addition to the above, is for the issuance of invitational travel orders, student screening purposes, and to determine the student's likes and dislikes; his/her recreation activities; dietary restrictions; etc.

The Security Cooperation Organization/Officer (SCO) collects the biographical data from International Military Students (IMS) to populate data tables in the SC-TMS. SCOs collect this information over the phone and/or in person. SCOs may access the system via username and password or if they are active DoW (civilian, military or contractor) members through Common Access Card and pin. Data may also be collected from automated uploads from the Regional Center Persons Activity Management System (RCPAMS) and Defense Security Assistance Management System (DSAMS) DoW systems; however, majority of IMS data is input directly into SCTMS by the SCO. Using the SC-TMS that is hosted on the Security Assistance Network

(SANWeb), the SCO enters the collected biographical data.

The IMS trains at United States Military schoolhouses. The IMSO at the schoolhouse/training activity logs onto SC-TMS to view the IMSI data and uses it to support the IMS while during their arrival and stay for training.

Dated: October 16, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026-21464 Filed 10-19-26; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Meeting of Department of Defense Federal Advisory Committee—Defense Policy Board

AGENCY: Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD (referred to herein as “the Department”, “Department of War” or “DoW”) is publishing this notice to announce the following federal advisory committee meeting of the Defense Policy Board (DPB) will take place.

DATES: Closed to the public; Tuesday, October 20, 2026, from 9:30 a.m. to 5:00 p.m. and Wednesday, October 21, 2026, from 9:00 a.m. to 12:00 p.m. The closed meetings will be held in the Rodman Conference Room, 3D852, at The Pentagon, 2000 Defense Pentagon, Washington, DC 20301-2000.

FOR FURTHER INFORMATION CONTACT: James E. Benkowski, DPB Designated Federal Officer (DFO), 703-697-4758 (Voice), james.e.benkowski2.civ@mail.mil (Email). Mailing address is 2000 Defense Pentagon, Attn: 5E420, Washington, DC 20301-2000.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of 5 United States Code (U.S.C.) chapter 10 of (commonly known as the “Federal Advisory Committee Act” or “FACA”); 5 U.S.C. 552b (commonly known as the “Government in the Sunshine Act”); and 41 Code of Federal Regulations (CFR) parts 102-3.140 and 102-3.150. Due to circumstances beyond the control of the (DFO, the DPB was unable to provide public notification required by 41 CFR part 102-3.150(a) concerning its October 20-21, 2026, meeting. Accordingly, the Advisory Committee Management Officer for the Department of War (DoW), pursuant to 41 CFR part 102-3.150(b), waives the seven-calendar day notification requirement.

Purpose of the Meeting: To obtain, review, and evaluate classified information related to the DPB's mission to assess the defense implications of various trade and economic policy issues as they relate to the DoW, including on: (a) How the DoW can best support and integrate with the Administration's trade and international economic strategy; (b) supercharging our Defense Industrial Base; (c) increasing burden-sharing with allies and partners; and (d) the potential effects and strategic implications of “China Shock 2.0.”

Agenda: On October 20 and 21, 2026, the DPB will receive classified briefings to assess the defense implications of various trade and economic policy issues as they relate to DoW strategic planning and other national security policy issues.

- Dr. James Benkowski, DPB DFO, will provide opening remarks; HON Elbridge Colby, Under Secretary of War for Policy (USW(P)), and AMB Robert Lighthizer, DPB Chair, will welcome the DPB and provide an overview of the meeting's purpose and its key objectives focused on the implications of various trade and economic policy issues. Subject matter experts from the USW (P) and the Office of the General Counsel will provide training on security and ethics, respectively, in an administrative session.

- Mr. James Ruocco, Performing the Duties of Assistant Secretary of War for Acquisition, will explain the DoW's approach to acquisition reform and supercharging the Defense Industrial Base in alignment with President Trump and Secretary Hegseth's guidance; and identify key issues for the DPB's consideration and action.

- Ambassador Jamieson Greer, United States Trade Representative, and HON Elbridge Colby, USW(P), will discuss ways that DoW strategic planning can best support and integrate with the Administration's trade and international economic strategy.

- Mr. Tom Sisk, Defense Intelligence Officer for China, will provide an intelligence update regarding Chinese perceptions on U.S. trade and economic policy as well as how potential responses to “China Shock 2.0” may influence the People's Republic of China calculus and behavior.

- AMB Robert Lighthizer will lead the DPB in drawing on its own expertise and experience to discuss key challenges and opportunities regarding the Administration's trade and economic strategy, and to deliberate in order to develop advice and recommendations for the Secretary of

War and the Deputy Secretary of War through the USW(P).

- Mr. David Copley, Senior Director, National Security Council, will lead a discussion with DPB members to better understand the administration's approach to securing supply chains and critical minerals.

- AMB Robert Lighthizer will again lead the DPB in drawing on its own expertise and experience to discuss key challenges and opportunities regarding the Administration's trade and economic strategy, and to deliberate in order to develop advice and recommendations for the Secretary of War and the Deputy Secretary of War through the USW(P).

- The DPB will then provide advice and recommendations to HON Elbridge Colby, USW(P).

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR part 102–3.155, the DoW has determined that this meeting shall be closed to the public. The USW(P), in consultation with the DoW FACA Attorney, has determined in writing that this meeting is closed to the public because the discussions fall under the purview of 5 U.S.C. 552b(c)(1) and are so inextricably intertwined with unclassified material that they cannot reasonably be segregated into separate discussions without disclosing classified material.

Written Statements: In accordance with 5 U.S.C. 1009(a)(3) and 41 CFR parts 102–3.140(c) and 102–3.150(6) the public or interested organizations may submit written statements to the membership of the DPB at any time regarding its mission or in response to the stated agenda of a planned meeting. Written statements should be submitted to the DPB's DFO, who's information is listed above in this notice in the **FOR FURTHER INFORMATION CONTACT** section or can be obtained from the General Services Administration (GSA) FACA Database—<http://www.facadatabase.gov/>. Written statements that do not pertain to a scheduled meeting of the DPB may be submitted at any time. However, if individual comments pertain to a specific topic being discussed at a planned meeting, then these statements must be submitted no later than one business day prior to the meeting in question in order for the DPB to consider the statement prior to or during the meeting. The DFO will review all submitted written statements and provide copies to all DPB members. Please note that all submitted comments and statements will be treated as public documents and will be made available for public inspection.

Dated: October 15, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026–21404 Filed 10–19–26; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2026–OS–0397]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD (referred to herein as “the Department”, “Department of War” or “DoW”) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by November 19, 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: Mr. Reginald Lucas, (571) 372–7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Pure Power; OMB Control Number 0704–MFPP.

Type of Request: New.

Number of Respondents: 17.

Responses per Respondent: 128.

Annual Responses: 2,176.

Average Burden per Response: 2 minutes.

Annual Burden Hours: 72.5.

Needs and Uses: This study is designed to assess the unique social, emotional and behavioral needs of military-connected youth, directly aligning with the administration's focus on service member readiness, retention, and optimized quality of life for their families.

Affected Public: Individuals and households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.
DOD Clearance Officer: Mr. Reginald Lucas.

Requests for copies of the information collection proposal should be sent to Mr. Lucas at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

Dated: October 16, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026–21465 Filed 10–19–26; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Department of the Navy

Certificate of Alternate Compliance for USS PATRICK GALLAGHER (DDG 127)

AGENCY: Department of the Navy, Department of Defense.

ACTION: Notice of Issuance of Certificate of Alternate Compliance.

SUMMARY: The U.S. Navy hereby announces that a Certificate of Alternate Compliance has been issued for USS PATRICK GALLAGHER (DDG 127). Due to the special construction and purpose of this vessel, the Admiralty Counsel of the Navy has determined it is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with the navigation lights provisions of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS) without interfering with its special function as a naval ship. The intended effect of this notice is to warn mariners in waters where 72 COLREGS apply.

DATES: This Certificate of Alternate Compliance is effective October 20, 2026 and is applicable beginning April 23, 2026.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Commander Jordan Foley, JAGC, U.S. Navy, Admiralty Attorney, Office of the Judge Advocate General, Admiralty and Claims Division (Code 15A), 1322 Patterson Ave. SE, Suite 3000, Washington Navy Yard, DC 20374–5066, 202–685–5040, or admiralty@us.navy.mil.

SUPPLEMENTARY INFORMATION:

Background and Purpose. Executive Order (E.O.) 11964 (42 FR 4327; January 19, 1977) and 33 U.S.C. 1605 provide that the requirements of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as to the number, position, range, or arc of visibility of lights or shapes, as well as to the disposition and characteristics of sound-signaling appliances, shall not

apply to a vessel or class of vessels of the Navy where the Secretary of the Navy shall find and certify that, by reason of special construction or purpose, it is not possible for such vessel(s) to comply fully with the provisions without interfering with the special function of the vessel(s). Notice of issuance of a Certificate of Alternate Compliance must be made in the **Federal Register**.

In accordance with 33 U.S.C. 1605, the Admiralty Counsel of the Navy, under authority delegated by the Secretary of the Navy, hereby finds and certifies that USS PATRICK GALLAGHER (DDG 127) is a vessel of special construction or purpose, and that, with respect to the position of the following navigational lights, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS without interfering with the special function of the vessel: Annex I, paragraph 3(a), pertaining to the position of the forward masthead light; Annex I, paragraph 2(f)(i) pertaining to the vertical position of the aft masthead light; Annex I, paragraph 3(a), pertaining to the horizontal distance between the masthead lights; Annex I, paragraph 3(c), pertaining to the horizontal distance of the "task lights" below the masthead lights; Annex I, paragraph 2(f)(ii), pertaining to the horizontal position of the task lights above the aft masthead light(s) and vertical position of the task lights between the forward masthead light(s) and aft masthead light(s).

The Admiralty Counsel of the Navy further finds and certifies that these navigational lights are in closest possible compliance with the applicable provision of the 72 COLREGS.

(Authority: 33 U.S.C. 1605(c), E.O. 11964.)

M.A. Tabach,

Lieutenant Commander, Judge Advocate General's Corps, U. S. Navy, Federal Register Liaison Officer.

[FR Doc. 2026-21463 Filed 10-19-26; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF DEFENSE

Department of the Navy

Certificate of Alternate Compliance for USS Harrisburg (LPD 30)

AGENCY: Department of the Navy, Department of Defense.

ACTION: Notice of Issuance of Certificate of Alternate Compliance.

SUMMARY: The U.S. Navy hereby announces that a Certificate of Alternate

Compliance has been issued for USS HARRISBURG (LPD 30). Due to the special construction and purpose of this vessel, the Admiralty Counsel of the Navy has determined it is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with the navigation lights provisions of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS) without interfering with its special function as a naval ship. The intended effect of this notice is to warn mariners in waters where 72 COLREGS apply.

DATES: This Certificate of Alternate Compliance is effective October 20, 2026 and is applicable beginning August 20, 2026.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Commander Colette K. Tolbert, JAGC, U.S. Navy, Admiralty Attorney, Office of the Judge Advocate General, Admiralty and Claims Division (Code 15A), 1322 Patterson Ave. SE, Suite 3000, Washington Navy Yard, DC 20374-5066, 202-685-8386, or admiralty@us.navy.mil.

SUPPLEMENTARY INFORMATION:

Background and Purpose. Executive Order (E.O.) 11964 (42 FR 4327; January 19, 1977) and 33 U.S.C. 1605 provide that the requirements of the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as to the number, position, range, or arc of visibility of lights or shapes, as well as to the disposition and characteristics of sound-signaling appliances, shall not apply to a vessel or class of vessels of the Navy where the Secretary of the Navy shall find and certify that, by reason of special construction or purpose, it is not possible for such vessel(s) to comply fully with the provisions without interfering with the special function of the vessel(s). Notice of issuance of a Certificate of Alternate Compliance must be made in the **Federal Register**.

In accordance with 33 U.S.C. 1605, the Admiralty Counsel of the Navy, under authority delegated by the Secretary of the Navy, hereby finds and certifies that USS HARRISBURG (LPD 30) is a vessel of special construction or purpose, and that, with respect to the position of the following navigational lights, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS without interfering with the special function of the vessel: Annex I, Paragraph 2(i)(i) pertaining to the vertical position of the task lights in relation to one another; Annex I, Paragraph 3(a), pertaining to the horizontal separation of the masthead lights; Annex I, Paragraph 2

(k), pertaining to the vertical separation of the anchor lights.

The Admiralty Counsel of the Navy further finds and certifies that these navigational lights are in closest possible compliance with the applicable provision of the 72 COLREGS.

(Authority: 33 U.S.C. 1605(c), E.O. 11964.)

M.A. Tabach,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2026-21456 Filed 10-19-26; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF EDUCATION

Notice Announcing From Seedlings to Scale and Transformative Research in Special Education Grants Programs

AGENCY: Department of Education.

ACTION: Notice.

SUMMARY: The Institute of Education Sciences (IES) at the U.S. Department of Education (ED) is soliciting applications for new awards of the Fiscal Year (FY) 2027 From Seedlings to Scale and Transformative Research in Special Education grants programs, Assistance Listing Numbers (ALNs) 84.305J and 84.324T.

DATES: Complete proposals must be submitted electronically through the [Grants.gov](https://grants.gov) "APPLY" function by 11:59:59 p.m. Eastern time December 11, 2026.

FOR FURTHER INFORMATION CONTACT:

Akilah Nelson for the 84.305J From Seedlings to Scale Grants Program. Telephone: (202) 804-7493. Email: Akilah.Nelson@ed.gov.

Courtney Pollack for the 84.324T Transformative Research in Special Education. Telephone: (202) 987-0071. Courtney.Pollack@ed.gov.

SUPPLEMENTARY INFORMATION: The FY 2027 application notices and instructions include program foci, requirements, and scientific peer review criteria for each competition listed below. IES is announcing the following competitions:

National Center for Education Research (NCER) Competition: From Seedlings to Scale Grants Program (ALN 84.305J). Under this competition, NCER will consider only Phase One applications that address the "C-STEP—Coordinating Systems to Translate Evidence into Policy and Practice" focus area.

National Center for Special Education Research (NCSER) Competition: Transformative Research in Special

Education (ALN 84.324T). Under this competition, NCSER will consider only Phase One applications that propose to research and develop transformative solutions to dramatically improve preservice teacher education systems so they can better attract, train, and retain preK–12 general and special education teachers who are prepared to provide high-quality instruction and substantially improve outcomes for students with or at risk for disabilities.

Maximum Award and Duration: For the From Seedlings to Scale Grants Program (ALN 84.305J), the maximum Phase One award is \$500,000 for a one-year project period. For the Transformative Research in Special Education (ALN 84.324T) program, the maximum Phase One award is \$3,750,000 for a three-year project.

Eligible Applicants: Institutions that have the ability and capacity to conduct scientifically valid research are eligible to apply. Eligible applicants include,

but are not limited to, institutions of higher education and non-profit, for-profit, public, or private organizations and entities.

Program Authority: 20 U.S.C. 9501 *et seq.*

To Apply: The complete funding opportunity announcements and all information needed to apply, including program requirements, are available on ED's website at <https://ies.ed.gov/funding/grants> and on *Grants.gov* at:

Name and ALN	Grants.gov link
From Seedlings to Scale Grants Program (ALN 84.305J)	https://grants.gov/search-results-detail/364086 .
Transformative Research in the Education Sciences (ALN 84.324T)	https://grants.gov/search-results-detail/364087 .

The application notices and instructions on *Grants.gov* are the official documents governing these grant competitions.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format.

Matthew Soldner,

Acting Director, Institute of Education Sciences.

[FR Doc. 2026–21427 Filed 10–19–26; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–531]

Application for Authorization To Export Electric Energy; Clear Power LLC

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Clear Power LLC (the Applicant or Clear Power) has applied for authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments must be submitted on or before November 19, 2026.

ADDRESSES: Comments or requests for more information should be addressed by electronic mail to Electricity.Exports@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Marina Fennel, (240) 702–6156, Electricity.Exports@hq.doe.gov.

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C.

824a(e)) and regulations thereunder (10 CFR 205.300). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export (16 U.S.C. 824a(e)). On January 8, 2026, the authority to issue such orders was delegated to the DOE's Assistant Secretary for the Office of Electricity by Redelegation Order No. S3–DEL–OE1–2026.

On April 16, 2026, Clear Power filed an application (Application or App.) with DOE for renewal of export authority to transmit electric energy from the United States to Mexico for an additional five-year term. App. at 1. Clear Power was originally granted export authorization under Order No. EA–487 on December 9, 2020, which expired on December 9, 2025. Since Clear Power did not apply for renewal until after the expiration of the current export authorization, DOE is processing the application as a request for a new export authorization.

According to the Application, Clear Power is a limited liability corporation with its principal place of business in Folsom, California. The Applicant is a power marketer with “authorization from the Federal Energy Regulatory Commission (FERC) to market electric energy and capacity at wholesale pursuant to market-based rate authorization.” *Id.* at 2. Clear Power states that it is a “wholly-owned subsidiary of the Alaywan Trust, which owns or is affiliated with entities that own or control a combined total of 18.0 MW (nameplate) of operating renewable generation facilities all located in the California Independent System Operator

(CAISO) market.” *Id.* Clear Power “does not own or control any electric power generation, transmission distribution facilities” and “does not have a franchised service area” *Id.* at 3. Thus, the Applicant states that it has “no ‘transmission system’ of its own on which power exports could have a reliability or stability impact.” *Id.* at 5. Clear Power “will schedule its exports from the U.S. in compliance with all applicable reliability criteria, standards and guides as are set out by the North American Electricity Reliability Corporation (NERC) (or any successor organization), the North American Energy Standards Board (or any successor organization) and regional reliability councils and as applied by U.S. transmission providers.” *Id.* at 5–6.

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App. at Exhibit C.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment to the Application at Electricity.Exports@hq.doe.gov.

Comments concerning Clear Power's Application should be clearly marked with OE Docket No. EA–531. Comments will be posted along with the relevant application on the program website at www.energy.gov/oe/pending-applications.

A final decision will be made on the requested authorization after the environmental impacts have been evaluated consistent with the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321, *et seq.*), the DOE NEPA regulations at 10 CFR part 1021, and the DOE's NEPA

Implementing Procedures (June 2026) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application are available on the program website at www.energy.gov/oe/pending-applications or by emailing Electricity.Exports@hq.doe.gov.

Signing Authority

This document of the Department of Energy was signed on October 14, 2026, by Catherine Jereza, Assistant Secretary, Office of Electricity, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on October 16, 2026.

Treena V. Garrett,

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

[FR Doc. 2026-21424 Filed 10-19-26; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

[Docket No. 15-62-LNG]

Texas LNG Brownsville LLC; Request for Extension of Export Commencement Deadline

AGENCY: Hydrocarbons and Geothermal Energy Office, Department of Energy.

ACTION: Notice of request.

SUMMARY: The Hydrocarbons and Geothermal Energy Office (HGEO) of the Department of Energy (DOE) gives notice (Notice) of receipt of a request (Request), filed on September 28, 2026, by Texas LNG Brownsville LLC (Texas LNG). Texas LNG asks DOE to amend its existing authorization to export domestically produced liquefied natural gas (LNG) to non-free trade agreement countries set forth in DOE/FE Order No. 4489 (as amended)—specifically, to extend its current export commencement deadline. Texas LNG filed the Request under the Natural Gas Act (NGA).

DATES: Protests, motions to intervene, or notices of intervention, as applicable, and written comments are to be filed electronically as detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, November 19, 2026.

ADDRESSES:

Electronic Filing by email (Strongly encouraged): fergas@hq.doe.gov.

Postal Mail, Hand Delivery, or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (EX-31), Office of Global Energy Security, Hydrocarbons and Geothermal Energy Office, Forrestal Building, Room 3E-056, 1000 Independence Avenue SW, Washington, DC 20585.

Due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit filings electronically to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT:

Jennifer Wade or Peri Ulrey, U.S.

Department of Energy (EX-31), Office of Global Energy Security, Office of Strategic Resources, Hydrocarbons and Geothermal Energy Office, Forrestal Building, Room 3E-042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586-4749 or (202) 586-7893, jennifer.wade@hq.doe.gov or peri.ulrey@hq.doe.gov

Christina Williams, U.S. Department of Energy (GC-76), Office of the Assistant General Counsel for Energy Delivery and Resilience, Forrestal Building, Room 6D-033, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586-55281, christina.williams@doe.gov

SUPPLEMENTARY INFORMATION:

On February 10, 2020, in DOE/FE Order No. 4489, as amended,¹ DOE's Office of Fossil Energy (now known as the Hydrocarbons and Geothermal Energy Office)² authorized Texas LNG to export domestically produced LNG by vessel from the proposed Texas LNG Brownsville LLC Liquefied Natural Gas Export Project (Project), to be located at the Port of Brownsville, Texas, to any country with which the United States has not entered into a free trade agreement (FTA) requiring national

treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries), pursuant to Natural Gas Act section 3(a).³ Texas LNG is authorized to export this LNG in a volume equivalent to 204.4 billion cubic feet (Bcf) per year (Bcf/yr) of natural gas for a term extending through December 31, 2050.⁴

Under Order No. 4489, Texas LNG is required to “commence export operations using the planned Project no later than seven years from the date of issuance of this Order”—i.e., by February 10, 2027.⁵ In the Request, Texas LNG asks DOE to extend this export commencement deadline by five years, to February 10, 2032.⁶

In support of this Request, Texas LNG states that, in the period since the issuance of Order No. 4489, Texas LNG has proceeded actively and diligently to develop the Project toward a positive final investment decision (FID).⁷ Texas LNG states, however, that those good faith efforts have been “substantially frustrated” by extenuating circumstances outside of Texas LNG's control, most significantly due to six years of sustained litigation and remand proceedings challenging Federal Energy Regulatory Commission's (FERC's) authorization to site, construct and operate the Project by a joint group of opponents.⁸ Texas LNG states that “[t]his uncertainty made it more difficult for Texas LNG to secure the long-term financing and commercial commitments necessary to reach FID and meet its current export commencement deadline.”⁹

Texas LNG adds that, on August 21, 2025, the FERC granted Texas LNG's request for an extension of its existing construction and in-service deadline for the Project until November 22, 2029.¹⁰ Texas LNG asserts that the requested commencement extension until February 10, 2032, will provide Texas LNG with additional time after FERC's current construction and in-service deadline to execute commercial commitments and begin exports.¹¹

Additionally, Texas LNG asks DOE to authorize an additional three-year make-up period at the end of its existing

³ 15 U.S.C. 717b(a).

⁴ See DOE/FE Order No. 4489-A, at 10 (Ordering Para. C).

⁵ DOE/FE Order No. 4489, at 55 (Ordering Para. D).

⁶ See Texas LNG Brownsville LLC, Request for Extension of Time, Docket No. 15-62-LNG, at 2, 5-6, 12 (Sept. 28, 2026) [hereinafter Request].

⁷ *Id.* at 7.

⁸ *Id.* at 4, 8-9.

⁹ *Id.* at 8-9.

¹⁰ *Id.* at 5, 9 (citing *Tex. LNG Brownsville LLC*, 192 FERC ¶ 61,170 (2025)).

¹¹ *Id.* at 6.

¹ *Texas LNG Brownsville LLC*, DOE/FE Order No. 4489, Docket No. 15-62-LNG, Opinion and Order Granting Long-Term Authorization to Export Liquefied Natural Gas to Non-Free Trade Agreement Nations (Feb. 10, 2020), amended by DOE/FE Order No. 4489-A (Dec. 10, 2020) (extending export term).

² The Office of Fossil Energy (FE) changed its name to the Office of Fossil Energy and Carbon Management (FECM) on July 4, 2021. Subsequently, on November 20, 2025, FECM changed its name to HGEO. DOE uses the acronym in effect at the time of each order or action discussed herein.

export authorization term through December 31, 2050, consistent with recent DOE practice.¹²

Additional details can be found in the Request, posted on the DOE website at <https://www.energy.gov/sites/default/files/2026-09/Texas%20LNG%20DOE%20EOT%20Request.pdf>.

DOE Evaluation

In reviewing the Request, DOE will consider any issues required by law or policy under NGA section 3(a), DOE's regulations, and any other documents deemed appropriate.

Parties that may oppose the Request should address these issues and documents in their comments and/or protests, as well as other issues deemed relevant to the Request.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable, addressing the Request. Interested parties will be provided 30 days from the date of publication of this Notice in the **Federal Register** in which to submit comments, protests, motions to intervene, or notices of intervention. The public previously was given an opportunity to intervene in, protest, and comment on Texas LNG's long-term non-FTA application in this docket. Therefore, DOE will not consider comments or protests that do not bear directly on this Request.

Any person wishing to become a party to this proceeding evaluating Texas LNG's Request must file a motion to intervene or notice of intervention.¹³ The filing of comments or a protest with respect to the Request will not serve to make the commenter or protestant a party to this proceeding, although protests and comments received from persons who are not parties will be

considered in determining the appropriate action to be taken on the Request. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by DOE's regulations in 10 CFR part 590, including the service requirements.

Filings may be submitted using one of the following methods:

(1) Submitting the filing electronically at fergas@hq.doe.gov;

(2) Mailing the filing to the Office of Global Energy Security at the address listed in the **ADDRESSES** section; or

(3) Hand delivering the filing to the Office of Global Energy Security at the address listed in the **ADDRESSES** section.

For administrative efficiency, DOE prefers filings to be filed electronically. All filings must include a reference to "Docket No. 15–62–LNG" or "Texas LNG's Request for Extension" in the title line. Filings must be submitted in English to be considered.¹⁴

For electronic submissions: Please include all related documents and attachments (e.g., exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner.

The Request, and any filed protests, motions to intervene, notices of intervention, and comments will be available electronically on the DOE website at www.energy.gov/hgeo/regulation.

A decisional record on the Request will be developed through responses to this Notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Order may be issued based on the official record, including the Request and responses filed by parties pursuant to this Notice, in accordance with 10 CFR 590.316.

Signed in Washington, DC, on October 15, 2026.

Amy Sweeney,

*Director, Office of Global Energy Security,
Office of Strategic Resources.*

[FR Doc. 2026–21425 Filed 10–19–26; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD26–8–000]

Reliability Technical Conference; Third Supplemental Notice of Commissioner- Led Technical Conference

As separately announced in the Notices of Technical Conference issued in this proceeding on June 11, 2026, and August 7, 2026, the Federal Energy Regulatory Commission (Commission) will convene its annual Commissioner-led Reliability Technical Conference, in the above-referenced proceeding, on Wednesday, October 21, 2026, from 10:00 a.m. to 2:40 p.m. Eastern Daylight Time, to discuss policy issues related to the reliability and security of the Bulk-Power System. The conference will be held in-person at the Commission's headquarters at 888 First Street NE, Washington, DC 20426 in the Kevin J. McIntyre Commission Meeting Room. The conference will be available to view online.

The purpose of this conference is to discuss policy issues related to the reliability and security of the Bulk-Power System. Attached to this Supplemental Notice is an agenda for the technical conference, which includes the technical conference program and expected panelists.

While the technical conference is not for the purpose of discussing any specific matters before the Commission, some discussions may involve issues raised in proceedings that are currently pending before the Commission. Any discussion on the merits of such proceedings will be curtailed. These proceedings include, but are not limited to:

PJM Interconnection, L.L.C	Docket Nos. EL26–67–000, EL26–67–001.
Midcontinent Independent System Operator, Inc	Docket Nos. EL26–70–000, EL26–70–001.
Southwest Power Pool, Inc	Docket No. EL26–68–000.
California Independent System Operator Corporation	Docket Nos. EL26–71–000, EL26–71–001.
ISO New England Inc	Docket Nos. EL26–72–000, EL26–72–001.
New York Independent System Operator Inc	Docket Nos. EL26–69–000, EL26–69–001.
PJM Interconnection, L.L.C	Docket No. ER26–3515–000.

¹² *Id.* at 2, 11–12.

¹³ Status as an intervenor in prior proceeding(s) in this docket does not continue to this proceeding evaluating Texas LNG's Request, and therefore any

person interested in intervening to address the Request must file a new motion to intervene (or notice of intervention, as applicable). 10 CFR 590.303.

¹⁴ See Executive Order 14224 of March 1, 2025, *Designating English as the Official Language of the United States*, 90 FR 11363 (Mar. 6, 2025).

PJM Interconnection, L.L.C	Docket No. ER26-3380-000.
PJM Interconnection, L.L.C	Docket No. ER26-1556-000.
Midcontinent Independent System Operator, Inc	Docket No. ER26-3552-000.
American Transmission Company LLC	Docket No. ER26-3265-000.
Midcontinent Independent System Operator, Inc	Docket No. ER26-3650-000.
Maryland Office of People's Counsel	Docket No. EL26-63-000.
International Transmission Co	Docket No. EL26-58-000.
PJM Interconnection, L.L.C	Docket Nos. EL25-49-003, AD24-11-000, EL25-20-002, ER26-1479-001, ER26-1479-002, EL24-149-000.
Duke Energy Carolinas, LLC	Docket No. ER26-2691-000.
Constellation Energy Generation, LLC	Docket Nos. EL25-20-000, EL25-20-001.
PJM Interconnection, L.L.C	Docket No. ER26-1088-000.
Tri-State Generation and Transmission Association, Inc	Docket No. ER26-1929-000.
American Transmission Company LLC	Docket No. ER26-3531-000.
Southwest Power Pool, Inc	Docket No. ER26-3720-000.
Southwest Power Pool, Inc	Docket No. ER26-2249-000.
PacifiCorp	Docket No. P-2420-000.
California Department of Water Resources	Docket No. P-2100-000.
Turlock Irrigation District	Docket No. P-2299-000.
Turlock Irrigation District and Modesto Irrigation District	Docket No. P-14581-000.
Gridflex Energy, LLC	Docket No. P-14851-000.
Pacific Gas and Electric Company	Docket No. P-77-000.
PacifiCorp	Docket No. P-2082-000.
PacifiCorp	Docket No. P-2381-000.
Idaho Power Company	Docket No. P-1971-000.
Idaho Power Company	Docket No. P-2736-000.
Fall River Rural Electric Cooperative	Docket No. P-5089-000.
Ada County and Fulcrum, Inc	Docket No. P-4881-000.
Big Wood Canal Company	Docket No. P-3407-000.
NorthWestern Company	Docket No. P-1869-000.
FFP Project 101, LLC	Docket No. P-14861-000.
City of Seattle	Docket No. P-553-000.
Black Canyon Hydro, LLC	Docket No. P-14787-000.
City of Pasadena Department of Water and Power	Docket Nos. P-1250-000, P-14836-000.
American Transmission Company LLC	Docket No. EL26-83-000.
Wolverine Power Supply Cooperative Inc	Docket No. ER26-3576-000.
Midcontinent Independent System Operator, Inc	Docket No. ER27-25-000.

The technical conference will be open to the public. Advance registration is not required, and there is no fee for attendance. Information will also be posted on the Calendar of Events on the Commission's website, www.ferc.gov, prior to the event.

The technical conference will be transcribed and webcast. Transcripts will be available for a fee from Ace Reporting (202-347-3700). A link to the webcast of this event will be available in the Commission Calendar of Events at www.ferc.gov. The Commission provides technical support for the free webcasts. Please call 202-502-8680 or email customer@ferc.gov if you have any questions.

Commission technical conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to accessibility@ferc.gov or call toll free 1-866-208-3372 (voice) or 202-208-8659 (TTY) or send a fax to 202-208-2106 with the required accommodations.

For more information about this conference, please contact Michael Gildea at Michael.Gildea@ferc.gov or (202) 502-8420 or Lodie White at Lodie.White@ferc.gov or (202) 502-8453.

Dated: October 15, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026-21435 Filed 10-19-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP27-3-000]

Double E Pipeline, LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on October 2, 2026, Double E Pipeline, LLC (Double E), 910 Louisiana Street, Suite 4200, Houston, Texas 77002, filed an application under section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations requesting authorization for its Texas Mainline Compressor Station Project (Project). The Project involves the installation of a new compressor station, consisting of two (2) natural gas-fired, turbine-driven centrifugal compressor units, totaling approximately 54,000 horsepower, along with associated piping, valves, controls, coolers, conditioning facilities,

cathodic protection, and appurtenances in Loving County, Texas. The Project will create an additional 800,000 dekatherms per day of firm transportation service on Double E's existing pipeline system.

Double E states that the Project responds to a growing need for firm pipeline capacity that connects expanding natural gas output from the Delaware Basin, a producing area within the Permian Basin, to the Waha Hub, a highly liquid trading point also within the Permian Basin with expanding takeaway capability. Double E states that the Project will also strengthen the reliability and operational flexibility of the Double E system across Texas and New Mexico and give the system the capability to reverse the direction of flow on its mainline. Double E estimates the total cost of the Project to be \$103,839,697 and proposes to use its existing recourse rates under Rate Schedule FTS as the applicable recourse rates for firm transportation service to be provided by the Project, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all

interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

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

Any questions regarding the proposed project should be directed to John Griffin, Vice President, Deputy General Counsel, Double E Pipeline, LLC, 910 Louisiana Street, Suite 4200, Houston, Texas 77002, by phone at (832) 930-7820, or by email at John.Griffin@summitmidstream.com.

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,¹ within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or

cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on November 5, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation (OPP) at (202) 502-6595 or OPP@ferc.gov.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)² and 385.211³ of the Commission's regulations under the NGA, any person⁴ may file a protest to the application. Protests must comply with the requirements specified in section 385.2001⁵ of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before 5:00 p.m. Eastern Time on November 5, 2026.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP27-3-000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select

the type of filing you are making; first select "General" and then select "Comment on a Filing"; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP27-3-000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. *However, the filing of a comment alone will not serve to make the filer a party to the proceeding.* To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,⁶ has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁷ and the regulations under the NGA⁸ by the intervention deadline for the project, which is 5:00 p.m. Eastern Time on November 5, 2026. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest

¹ 18 CFR 157.9.

² 18 CFR 157.10(a)(4).

³ 18 CFR 385.211.

⁴ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁵ 18 CFR 385.2001.

⁶ 18 CFR 385.102(d).

⁷ 18 CFR 385.214.

⁸ 18 CFR 157.10.

in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to/intervene.asp>.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP27–3–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Intervention." The eFiling feature includes a document-less intervention option; for more information, visit <https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf>; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP27–3–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail at: John Griffin, Vice President, Deputy General Counsel, Double E Pipeline, LLC, 910 Louisiana Street, Suite 4200, Houston, Texas 77002 or by email (with a link to the document) at John.Griffin@summitmidstream.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed⁹ motions to intervene are automatically granted by operation of Rule 214(c)(1).¹⁰ Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.¹¹ A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from OPP at (202) 502–6595 or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Intervention Deadline: 5:00 p.m. Eastern Time on November 5, 2026.

(Authority: 18 CFR 2.1)

Dated: October 15, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–21440 Filed 10–19–26; 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:

⁹ The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

¹⁰ 18 CFR 385.214(c)(1).

¹¹ 18 CFR 385.214(b)(3) and (d).

Filings Instituting Proceedings

Docket Numbers: RP27–42–000.

Applicants: Cheniere Corpus Christi Pipeline, LP.

Description: Compliance filing: Cheniere Corpus Christi Pipeline, L.P. Order No. 587–AB Compliance Filing to be effective 1/1/2027.

Filed Date: 10/14/26.

Accession Number: 20261014–5139.

Comment Date: 5 p.m. ET 10/26/26.

Docket Numbers: RP27–43–000.

Applicants: Cheniere Creole Trail Pipeline, L.P.

Description: Compliance filing: Cheniere Creole Trail Pipeline, L.P. Order No. 587–AB Compliance Filing to be effective 1/1/2027.

Filed Date: 10/14/26.

Accession Number: 20261014–5157.

Comment Date: 5 p.m. ET 10/26/26.

Docket Numbers: RP27–44–000.

Applicants: Carlsbad Gateway, LLC.

Description: Compliance filing: Carlsbad Gateway, LLC Order No. 587–AB Compliance Filing to be effective 1/1/2027.

Filed Date: 10/15/26.

Accession Number: 20261015–5036.

Comment Date: 5 p.m. ET 10/27/26.

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.

Filings in Existing Proceedings

Docket Numbers: RP26–1208–001.

Applicants: Monroe Gas Storage Company, LLC.

Description: Compliance filing: NAESB 4.0 Compliance Filing—Monroe to be effective 1/1/2027.

Filed Date: 10/14/26.

Accession Number: 20261014–5095.

Comment Date: 5 p.m. ET 10/26/26.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/>

docs-filing/efiling/filing-req.pdf. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

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: October 15, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026-21439 Filed 10-19-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD27-1-000]

Uma Lagne Energy Holdings, LLC; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On October 1, 2026, Uma Lagne Energy Holdings, LLC, filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed Buckeye Hydrokinetic PHX5 Project would have an installed capacity of 5 kilowatts (kW) and would be

located along the Buckeye Water Conservation and Drainage District's Buckeye Main Canal, near Buckeye, Maricopa County, Arizona.

Applicant Contact: Ryan Cook, 1115 Howell Mill Rd. NW, Atlanta, Georgia 30318, 614-619-0038, *ryan.cook@emrgy.com*.

FERC Contact: Christopher Chaney, 202-502-6778, *christopher.chaney@ferc.gov*.

Qualifying Conduit Hydropower Facility Description: The project would consist of: (1) one 5-kW modular hydrokinetic turbine, and (2) and appurtenant facilities.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 40 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed Buckeye Hydrokinetic PHX5 Project will not alter the primary purpose of the conduit, which is for agricultural consumption. Therefore, based upon the above criteria, Commission staff preliminarily determines that the operation of the project described above satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments, comments contesting whether the facility meets the qualifying criteria, and motions to intervene: November 16, 2026, 5:00 p.m. Eastern Time.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the "COMMENTS," "COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT

HYDROPOWER FACILITY," or "MOTION TO INTERVENE," as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.¹ All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

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 motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. You must include your name and contact information at the end of your comments. 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 send a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Locations of Notice of Intent: The Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp*. Enter the docket number (*i.e.*, CD27-1) in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/*

¹ 18 CFR 385.2001-2005 (2025).

esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects. Copies of the notice of intent can be obtained directly from the applicant. For assistance, call toll-free 1-866-208-3676 or email FERCOnlineSupport@ferc.gov. For TTY, call (202) 502-8659.

(Authority: 18 CFR 2.1)

Dated: October 15, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026-21436 Filed 10-19-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PL26-3-000]

Environmental Review of Natural Gas Act Applications; Notice of Availability of Draft Policy Statement on Efficient Environmental Reviews of Natural Gas Project Applications

The Federal Energy Regulatory Commission (FERC or Commission) has prepared a draft policy statement concerning the Commission's review of operational air emissions and associated air quality effects of proposed natural gas projects under the Natural Gas Act (NGA) and the National Environmental Policy Act (NEPA). Pursuant to the policy described in the draft statement, the Commission would no longer ordinarily ask applicants to prepare or submit air dispersion modeling for compressor stations or liquefied natural gas facilities, nor require use of the results of such modeling in assessing the air quality effects of such facilities under the NGA and NEPA. Instead, the Commission would use other information submitted by applicants and identified by Commission staff, including but not limited to information on governing state and federal air quality regulations and applicants' compliance therewith, to analyze the air quality effects of proposed projects.

The draft policy statement, for which the Commission seeks comment, can be found in Docket Number PL26-3-000. Any person wishing to comment on the draft policy statement may do so. To ensure consideration of your comments before issuance of the final version, it is important that the Commission receive your comments on or before 5:00 p.m. Eastern Time on November 16, 2026.

The Commission specifically seeks comment on the optimal implementation of its new policy, as opposed to its legal justification. Instructions for filing comments are provided below.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the docket number (PL26-3-000) with your submission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208-3676 or FercOnlineSupport@ferc.gov. Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's website (www.ferc.gov) under the link to FERC Online. This is an easy method for submitting brief, text-only comments;

(2) You can file your comments electronically by using the eFiling feature on the Commission's website (www.ferc.gov) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." If you are filing a comment on a particular project, please select "Comment on a Filing" as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the docket number (PL26-3-000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

All of the information related to the draft policy statement and submitted comments can be found on the FERC website (www.ferc.gov) using the eLibrary link. Click on the eLibrary link, click on "General Search" and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.*, PL26-3). Be sure you have selected an appropriate date range. For assistance, contact the Office of Public Participation at (202)502-6595 or OPP@ferc.gov.

ferc.gov. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

(Authority: 18 CFR 2.1)

Dated: October 15, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026-21442 Filed 10-19-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD06-6-000]

Notice of Joint Meeting of the Federal Energy Regulatory Commission and the Nuclear Regulatory Commission

The Federal Energy Regulatory Commission (FERC) and the Nuclear Regulatory Commission (NRC) will hold a joint open meeting on Thursday, October 22, 2026, from 1:00 p.m. to 3:30 p.m. Eastern Standard Time. The meeting will be held in-person at the U.S. Nuclear Regulatory Commission's headquarters, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738 in the Commissioners Hearing Room. Commissioners from both agencies are expected to participate.

The format for the joint meeting will consist of discussions between the two sets of Commissioners following presentations by their respective staffs. In addition, a representative of the North American Electric Reliability Corporation (NERC) will attend and participate in this meeting.

The meeting is not for the purpose of discussing the merits of any specific proceedings before FERC, and any such discussions will be curtailed. Proceedings before FERC raising possibly relevant issues include, but are not limited to:

Southwest Power Pool, Inc	Docket No. EL26–68–000.
California Independent System Operator Corporation	Docket Nos. EL26–71–000, EL26–71–001.
ISO New England Inc	Docket Nos. EL26–72–000, EL26–72–001.
New York Independent System Operator Inc	Docket Nos. EL26–69–000, EL26–69–001.

The meeting will be open for the public to attend. Pre-registration is not required and there is no fee for attendance. Information on this meeting will also be posted on the Calendar of Events on the Commission's website, www.ferc.gov, prior to the event. The meeting will also be transcribed. Transcripts will be available on NRC's website at: <https://www.nrc.gov/documents-reports/document-collections/commission-documents/commission-meetings-agendas-slides-transcripts-meeting-srms-and-full-written-explanation-for-closed-meetings/2026transcribe>.

Commission meetings are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to accessibility@ferc.gov, call toll-free (866) 208–3372 (voice) or (202) 208–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

All interested persons are invited to the meeting. Questions about the meeting should be directed to Lodie White at Lodie.White@ferc.gov or by phone at (202) 502–8453.

Dated: October 15, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026–21434 Filed 10–19–26; 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 Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL27–6–000; QF90–73–014.

Applicants: EF KENILWORTH, INC., EF Kenilworth LLC.

Description: Waiver of the Operating and Efficiency Standards for a Topping-Cycle of EF Kenilworth LLC.

Filed Date: 10/9/26.

Accession Number: 20261009–5190.

Comment Date: 5 p.m. ET 11/9/26.

Take notice that the Commission received the following Electric Rate filings:

Docket Numbers: ER26–3602–001.

Applicants: Neradean Energy Inc.

Description: Tariff Amendment: Deficiency Response to be effective 8/25/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5017.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–148–000.

Applicants: US–PR Transmission Line LLC.

Description: § 205(d) Rate Filing: US–PR Transmission Line LLC Initial Baseline Market-Based Rate Tariff to be effective 10/1/2029.

Filed Date: 10/14/26.

Accession Number: 20261014–5168.

Comment Date: 5 p.m. ET 11/4/26.

Docket Numbers: ER27–149–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of SA No. 6787; Queue Position No. MISO J857 to be effective 12/15/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5020.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–150–000.

Applicants: Duke Energy Carolinas, LLC.

Description: Tariff Amendment: DEC–DEC Notice of Termination of E&P Agmts RS Nos. 704, 705 and 706 to be effective 12/15/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5022.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–151–000.

Applicants: Duke Energy Carolinas, LLC.

Description: Tariff Amendment: DEC–Piedmont EMC Notice of Termination of NITSA SA No. 368 to be effective 12/31/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5023.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–152–000.

Applicants: Duke Energy Progress, LLC.

Description: Tariff Amendment: DEP–Notice of Termination of Piedmont EMC NITSA SA No. 322 to be effective 12/31/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5034.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–153–000.

Applicants: Citizens Sunrise Transmission LLC.

Description: § 205(d) Rate Filing: Annual TRBAA Filing to be effective 1/1/2027.

Filed Date: 10/15/26.

Accession Number: 20261015–5039.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–154–000.

Applicants: Citizens Sycamore-Penasquitos Transmission LLC.

Description: § 205(d) Rate Filing: Annual TRBAA Filing to be effective 1/1/2027.

Filed Date: 10/15/26.

Accession Number: 20261015–5044.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–155–000.

Applicants: Citizens S-Line Transmission LLC.

Description: § 205(d) Rate Filing: Annual TRBAA Filing to be effective 1/1/2027.

Filed Date: 10/15/26.

Accession Number: 20261015–5047.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–156–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of SA No. 6776; Queue Position No. MISO J875 to be effective 12/15/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5049.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–157–000.

Applicants: Consolidated Edison Company of New York, Inc.

Description: § 205(d) Rate Filing: Revised Accommodation Services Tariff filing to be effective 12/15/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5065.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–158–000.

Applicants: ISO New England Inc.

Description: § 205(d) Rate Filing: 2027 Capital Budget and Rev. Tariff Sheets for Recovery of 2027 Admin. Costs to be effective 12/15/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5075.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–159–000.

Applicants: Kyan Solar, LLC.

Description: Initial Rate Filing: Kyan Solar, LLC—Baseline Filing to be effective 10/16/2026.

Filed Date: 10/15/26.

Accession Number: 20261015–5083.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27–160–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: DEC—Amended and Restated Dynamic

Transfer Agreements to be effective 12/31/9998.

Filed Date: 10/15/26.

Accession Number: 20261015-5084.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27-161-000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: ESM Const Agmt McNary-WallaWalla (S.A. No. 1229) to be effective 12/15/2026.

Filed Date: 10/15/26.

Accession Number: 20261015-5096.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27-162-000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: UAMPS TSOA Rev 13 (R.S. No. 297) to be effective 12/15/2026.

Filed Date: 10/15/26.

Accession Number: 20261015-5098.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27-163-000.

Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2026-10-15 SA 4439 ATC-Copper Country Power I FSA (J1814 J2316) to be effective 10/5/2026.

Filed Date: 10/15/26.

Accession Number: 20261015-5100.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27-164-000.

Applicants: ISO New England Inc.

Description: § 205(d) Rate Filing: Revised Tariff Sheets for Recovery of Costs for the 2027 Operation of NESCOE to be effective 1/1/2027.

Filed Date: 10/15/26.

Accession Number: 20261015-5112.

Comment Date: 5 p.m. ET 11/5/26.

Docket Numbers: ER27-165-000.

Applicants: LS Power Grid California, LLC.

Description: § 205(d) Rate Filing: LSPG CA, LLC Annual TRBA Adjustment and Projected Revenue Requirement Filing to be effective 1/1/2027.

Filed Date: 10/15/26.

Accession Number: 20261015-5118.

Comment Date: 5 p.m. ET 11/5/26.

Take notice that the Commission received the following Electric Securities filings:

Docket Numbers: ES27-4-000.

Applicants: Keystone Appalachian Transmission Company.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Keystone Appalachian Transmission Company.

Filed Date: 10/14/26.

Accession Number: 20261014-5194.

Comment Date: 5 p.m. ET 11/4/26.

Docket Numbers: TS26-10-000.

Applicants: City of Hastings, Nebraska d/b/a Hastings Utilities.

Description: The City of Hastings, Nebraska d/b/a Hastings Utilities submits Request for Waiver of Standards of Conduct requirements.

Filed Date: 9/30/26.

Accession Number: 20260930-5090.

Comment Date: 5 p.m. ET 10/21/26.

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: October 15, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026-21438 Filed 10-19-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP27-4-000]

Equitrans, L.P.; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on October 7, 2026, Equitrans, L.P. (Equitrans), 2200 Energy Drive, Canonsburg, Pennsylvania 15317, filed in the above-referenced docket a prior notice request pursuant to sections 157.205, 157.213(b), and 157.216(b) of the Commission's regulations under the Natural Gas Act (NGA), and Equitrans' blanket certificate issued in Docket No. CP96-532-000, for authorization to plug and abandon the Pratt 3647 withdrawal storage well, remove associated valves, and abandon approximately 485 feet of

six-inch-diameter natural gas pipeline. All of the above facilities are located in Greene and Washington Counties, Pennsylvania (Pratt 3647 Plug and Abandonment Project). The project will enable Equitrans to meet the Pipeline and Hazardous Materials Safety Administration (PHMSA) requirements regarding storage wells. The estimated cost for the project is approximately \$1.2 million, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

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

Any questions concerning this request should be directed to Jennifer Brough, Sheppard, Mullin, Richter & Hampton LLP, Four Embarcadero Center, 17th Floor, Francisco, CA 94111-4109, by phone at (415) 434-9100, or by email at jbrough@sheppard.com.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on December 14, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public

Participation (OPP) at (202) 502–6595 or OPP@ferc.gov.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,¹ any person² or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,³ and must be submitted by the protest deadline, which is 5:00 p.m. Eastern Time on December 14, 2026. Filings that do not meet requirements of 18 CFR 157.205(e)(2)⁴ will not be considered protests by the Commission.⁵ A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁶ and the regulations under the NGA⁷ by the intervention deadline for the project, which is 5:00 p.m. Eastern Time on December 14, 2026. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist.

You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to/intervene.asp>.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before 5:00 p.m. Eastern Time on December 14, 2026. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP27–4–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Protest", "Intervention", or "Comment on a Filing" or⁸

(2) You can file a paper copy of your submission by mailing it to the address

below. Your submission must reference the Project docket number CP27–4–000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other method: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail at: Jennifer Brough at Sheppard, Mullin, Richter & Hampton LLP, Four Embarcadero Center, 17th Floor, San Francisco, CA 94111–4109, or by email (with a link to the document) at jbrough@sheppard.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking The Proceeding

Throughout the proceeding, additional information about the project will be available from OPP at (202) 502–6595 or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

(Authority: 18 CFR 2.1)

Dated: October 15, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026–21441 Filed 10–19–26; 8:45 am]

BILLING CODE 6717–01–P

¹ 18 CFR 157.205.

² Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

³ 18 CFR 157.205(e).

⁴ 18 CFR 157.205(e)(2).

⁵ *Cheniere Creole Trail Pipeline, L.P.*, 195 FERC ¶ 61,208, at P 8 n.16 (2026).

⁶ 18 CFR 385.214.

⁷ 18 CFR 157.10.

⁸ Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. CD27–2–000]

Zushi Renewables, LLC; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On October 1, 2026, and supplemented on October 13, 2026, Zushi Renewables, LLC, filed a notice of

intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed Arvin Edison Canal Hydrokinetic 1 Project would have an installed capacity of 40 kilowatts (kW) and would be located along the Arvin-Edison Water Storage District's Intake Canal, near Bakersfield, Kern County, California.

Applicant Contact: Ryan Cook, 1115 Howell Mill Rd. NW, Atlanta, Georgia 30318, 614–619–0038, ryan.cook@emrgy.com.

FERC Contact: Christopher Chaney, 202–502–6778, christopher.chaney@ferc.gov.

Qualifying Conduit Hydropower Facility Description: The project would consist of: (1) four 10-kW modular hydrokinetic twin turbines, for a total capacity of 40 kW, and (2) and appurtenant facilities.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 40 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed Arvin Edison Canal Hydrokinetic 1 Project will not alter the primary purpose of the conduit, which is for agricultural consumption. Therefore, based upon the above criteria, Commission staff preliminarily determines that the operation of the project described above satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments, comments contesting whether the facility meets the qualifying criteria, and motions to intervene: November 16, 2026, 5:00 p.m. Eastern Time.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the “COMMENTS,” “COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY,” or “MOTION TO INTERVENE,” as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the

filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.¹ All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

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 motions to intervene and comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. You must include your name and contact information at the end of your comments. 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 send a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier

must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Locations of Notice of Intent: The Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's website at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number (i.e., CD27–2) in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. Copies of the notice of intent can be obtained directly from the applicant. For assistance, call toll-free 1–866–208–3676 or email FERCOnlineSupport@ferc.gov. For TTY, call (202) 502–8659.

(Authority: 18 CFR 2.1.)

Dated: October 15, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026–21437 Filed 10–19–26; 8:45 am]

BILLING CODE 6717–01–P

¹ 18 CFR 385.2001–2005 (2025).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–27–0057]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Agency for Toxic Substances and Disease Registry (ATSDR) has submitted the information collection request titled “APPLETREE Performance Measures” to the Office of Management and Budget (OMB) for review and approval. ATSDR previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on June 26, 2026 to obtain comments from the public and affected agencies. ATSDR received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

ATSDR will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the

search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

APPLETREE Performance Measures (OMB Control No. 0923–0057, Exp. 10/31/2026)—Revision—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Agency for Toxic Substances and Disease Registry (ATSDR) seeks to build and sustain the capacity to evaluate exposures to hazardous waste across the country. Releases from hazardous waste sites are a major source of harmful exposures in homes, schools, workplaces, and communities. These exposures are often complex and may be difficult to identify and control. Hazardous waste sites may involve various toxic substances, exposure pathways, and health impacts. ATSDR’s primary goal is to keep communities safe from harmful exposures and related diseases. To accomplish this goal, the agency works closely with partnering agencies to evaluate exposures at hazardous waste sites, educate communities, and seek new ways to better protect public health.

ATSDR’s Partnership to Promote Local Efforts to Reduce Environmental Exposure (APPLETREE) Program is critical to ATSDR’s success in accomplishing its mission in communities nationwide. ATSDR’s recipients will use APPLETREE funding to advance ATSDR’s primary goal of keeping communities safe from harmful environmental exposures and related diseases. APPLETREE gives recipients the resources to build their capacity to assess and respond to site-specific issues involving human exposure to hazardous substances in the environment. APPLETREE helps recipients identify exposure pathways at specific sites; educate affected communities about site contamination and potential health effects; make recommendations to prevent exposure; review health outcome data to evaluate potential links between site contaminants and community health outcomes. APPLETREE facilitates the implementation of state-level programs to ensure that potential early care and education facilities are in areas free from harmful environmental exposures. Additionally, it motivates the recipients

to innovate and implement progressive public health interventions that can prevent exposure to environmental contamination. Due to the local connections and partnerships of APPLETREE recipients, there is an enhancement in community engagement and implementation of recommendations. This program is authorized under Sections 104(i)(15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 [42 U.S.C. 9604(i)(15)].

Under the current five-year APPLETREE cooperative agreement (NOFO No. CDC–RFA–TS–23–0001), eligible applicants include federally recognized American Indian/Alaska Native tribal governments; American Indian/Alaska native tribally designated organizations; political subdivisions of states (in consultation with states); and state and local governments or their bona fide agents. ATSDR technical project officers (TPOs) assist 30 APPLETREE recipients to address site-specific issues involving human exposure to hazardous substances. Key capacities include identification of human exposure pathways at ATSDR sites, education of affected communities and local health professionals about site contamination and potential health effects; making appropriate recommendations to prevent exposure; reviewing health outcome data to evaluate potential links between site contaminants and community health; and documenting the effects of environmental remediation on health.

This is a Revision of an information collection request (ICR) titled “APPLETREE Performance Measures,” previously approved under OMB Control No. 0923–0057 (Exp. 10/31/2026). ATSDR will continue to collect information related to recipient activities, and the process and outcome performance measures outlined by the cooperative agreement program. Information will be used to monitor progress toward program goals and objectives, and for program quality improvement. All forms were previously approved by OMB.

1. *ATSDR Health Education (HE) Activity Form:* For each environmental health assessment and health education activity conducted at ATSDR sites, APPLETREE recipients will quantitatively assess and report efforts to educate community members about site recommendations and health risks using indicators to assess community understanding of site findings about health risks and community

understanding of agency recommendations to reduce health risks.

2. *ATSDR Technical Assistance (TA) Activity Form*: Throughout the budget year, this form will be used to record the routine requests made by the recipients and their program responses. These responses do not evaluate environmental data and do not make health calls but are monitored by ATSDR as part of the recipients' performance.

3. *ATSDR Site Impact Assessment (SIA) Form*: For each environmental health assessment and health education activity conducted at ATSDR sites, recipients shall estimate and report the number of people protected from exposure to toxic substances at each site where implementation of agency recommendations has taken place and at each childcare center where safe siting guidelines have been implemented. To the extent possible, recipients shall estimate and report the disease burden prevented due to the implementation of site recommendations and safe siting guidelines.

4. *ATSDR Success Story Form*: Recipients will provide one success story per quarter (four success stories total per year) that highlights the impact of any of their programs. Recipients will report a summary, background, intervention/action taken, and accomplishment/impact for each story. Optionally, they may include a photo or quote.

5. *APPLETREE Annual Performance Report (APR) Template*: Recipients will continue to provide an APR each year and at the end of the funding cycle, which summarizes their annual and funding cycle performances, respectively. APRs will be due in December of each year to coincide with the CDC Grants Management annual

reports to reduce the overall reporting burden, and the final report will be due at the end of the funding cycle. The purpose of the performance reports will be to assess Partners based on performance measures and evaluation projects. The reports should include a summary of performance measures, results of any evaluation projects, an accompanying narrative of progress and interpretation of results, optional successes, challenges, and an updated work plan.

6. *Choose Safe Places for Early Care and Education (CSPECE) Qualitative Narrative Form*: Recipients will continue to provide a narrative report of their CSPECE Programs to document descriptive details of their state's landscape, program plan, program implementation, and results that cannot be captured through numbers. Recipients will complete and submit the narrative once a year as a supplement with their APRs.

7. *CSPECE Quantitative Form*: Recipients will continue to provide data on their CSPECE Programs to quantify aspects of their program such as children reached, target audiences educated, early care and education programs referred and screened, and recommendations implemented. To supplement their APRs, recipients will complete and submit once a year as a supplement with their APRs. In addition to the required annual reporting, at the end of the five-year program, each recipient will report cumulative five-year performance measures for three forms: the APR, the CSPECE Qualitative Narrative Form, and the CSPECE Quantitative Form. This will result in six total responses in a five-year period for each form. The estimated annualized number of required responses is thus rounded to

once per year for these three forms, as 6 hours divided by three years equals 1.2 hours per year.

8. *ATSDR SoilSHOP Form*: SoilSHOPS are not a required activity; however, if conducted, a recipient will need to complete the ATSDR SoilSHOP Form. This form gathers data on the inputs, activities, outputs, and outcomes of the event, such as the number of soil samples screened, the number of elevated soil samples, the number of individuals receiving health consultations, and the number of individuals receiving referrals.

9. *ATSDR Recommendation Follow-up Form*: For each environmental health assessment, recipients will provide an update on the status of acceptance and implementation of all recommendations to understand whether and how recommendations have been implemented, and the subsequent impact on communities. Recipients will report annually on the anniversary date of the release of each health assessment.

10. *ATSDR Requests for Certified and Non-certified Public Health Assessments and Health Consultations Form*: For each environmental health assessment, recipients will provide the request, dates, and triage information and can associate the request with a hazardous waste site. Site scoping and clearance information are completed for about 15% of environmental health assessments that complete ATSDR's clearance process (*i.e.*, certified).

ATSDR is seeking a three-year Paperwork Reduction Act (PRA) clearance for this Revision ICR. ATSDR currently funds 30 recipients, and recipient reporting is required to receive funding under the APPLETREE cooperative agreement. The total annual time burden requested is 336 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
APPLETREE Recipients	ATSDR Health Education (HE) Activity Form	30	17	4/60
	ATSDR Technical Assistance (TA) Activity Form	30	17	4/60
	ATSDR Site Impact Assessment (SIA) Form	30	3	7/60
	ATSDR Success Story Form	30	4	1
	APPLETREE Annual Performance Report (APR) Template	30	1	2
	Choose Safe Places for Early Care and Education (CSPECE) Qualitative Narrative Form.	30	1	1
	CSPECE Quantitative Form	30	1	30/60
	ATSDR SoilSHOP Form	10	1	7/60
	ATSDR Recommendation Follow-up	30	4	10/60
	ATSDR Requests	30	3	7/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.

[FR Doc. 2026–21416 Filed 10–19–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–27–1417]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “Public Health Emergency Management Capacity Assessment Tool (PHEM Tool)” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on June 18, 2026 to obtain comments from the public and affected agencies. CDC received four comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Public Health Emergency Management Capacity Assessment Tool (PHEM Tool) (OMB Control No. 0920–1417, Exp. 10/31/2026)—Extension—Office of Readiness and Response (ORR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention’s (CDC) Global Emergency Management Capacity Development (GEMCD) team strengthens emergency management capacity development globally. It helps countries to prepare for, anticipate, and respond to all forms of public health threats. GEMCD’s mission is to build resilient Public Health Emergency Management (PHEM) programs throughout the world. The GEMCD team’s Emergency Management Technical Advisors (EMTAs) use the PHEM Tool to guide an in-person interview with GHSA countries Ministry of Health, Public Health Emergency Operations Center (PHEOC) Manager and optional additional staff, to characterize the country’s PHEM program and capabilities. EMTAs document responses in an excel-based form that are entered into and maintained in the CDCReady database.

Collected data identify strengths and weaknesses, capabilities, and gaps in PHEM programs and PHEOCs in GHSA countries. Findings guide GEMCD team program planning initiatives and determine appropriate technical assistance (TA) for GHSA countries. Data is analyzed to identify the presence or absence of specific PHEM and PHEOC requirements, such as plans, policies, and procedures, etc. Additional analysis focuses upon the status of PHEM and PHEOC plans, policies, and procedures, (e.g., date of publication, relevance). The survey is conducted annually to identify progress and document changes from one year to the next in terms of PHEM program and PHEOC capabilities.

CDC requests OMB approval for three years. The estimated annualized burden for this information collection is 72 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Ministry of Health personnel responsible for Public Health Emergency Management (PHEM) Program in participating GHSA countries.	PHEM Tool	12	1	6

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.

[FR Doc. 2026–21417 Filed 10–19–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-D-6501]

New Dietary Ingredient (NDI) Notifications and Related Issues; Identity and Safety Information About the NDI: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled “New Dietary Ingredient (NDI) Notifications and Related Issues; Identity and Safety Information About the NDI: Guidance for Industry.” The guidance focuses on frequently asked questions about the new dietary ingredient notification (NDIN) submissions. This guidance is intended to help provide recommendations to manufacturers and distributors of NDIs and dietary supplements containing an NDI regarding the identity and safety information that should be included in an NDIN.

DATES: The announcement of the guidance is published in the **Federal Register** on October 20, 2026.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a

written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2025-D-6501 for “New Dietary Ingredient (NDI) Notifications and Related Issues; Safety Information About the NDI: Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Dietary Supplement Programs, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Gerie Voss, Office of Dietary Supplement Programs, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-620-9744; or Lauren Kleinman, Division of Human Foods Regulations, Office of Regulations & International Programs, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled “New Dietary Ingredient (NDI) Notifications and Related Issues; Identity and Safety Information About the NDI: Guidance for Industry.” We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of July 5, 2011 (76 FR 39111), we announced the availability of a draft guidance for industry entitled “Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues” and gave interested parties an opportunity to submit comments by October 3, 2011. Among other topics, the July 2011 draft

guidance discussed FDA's views and recommendations on when an ingredient intended for use in a dietary supplement is an NDI, when the requirement to submit an NDIN to FDA applies, the types of data and information that manufacturers and distributors should consider when they evaluate the safety of a dietary supplement containing an NDI, what to include in an NDIN (including recommendations about identity and safety information), and the procedures for submitting an NDIN. We received significant comments and decided to issue a revised draft guidance.

In the **Federal Register** of August 12, 2016 (81 FR 53486), we announced the availability of a revised draft guidance for industry entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry" to replace the July 2011 draft guidance. We gave interested parties an opportunity to submit comments on the 2016 revised draft guidance by October 11, 2016. On October 4, 2016, we extended the comment period for the revised draft guidance to December 12, 2016 (81 FR 68434).

The final guidance, whose availability we are announcing through this document, finalizes in a stand-alone document the identity and safety recommendations that had been in sections VI.A, "Identity Information about the NDI and the Dietary Supplement," VI.B, "History of Use or Other Evidence of Safety," and VI.C, "Summary of the Basis for Your Conclusion of Safety," of the 2016 draft guidance. To help alleviate the burden of submitting separate documents regarding the safety data submitted in an NDIN, we eliminated the references to a "comprehensive safety profile" and, instead, recommend use of a single "safety narrative" for all NDINs. We made changes to provide additional clarity and description regarding what should be included in the NDIN safety narrative, when additional evidence of safety should be submitted, and what types of studies are recommended to support an NDIN. Finally, the guidance contains editorial changes to improve clarity.

FDA has also updated the 2016 revised draft guidance to indicate which portions have been finalized and which portions remain in draft status (see <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-new-dietary-ingredient-notifications-and-related-issues>).

FDA considered the applicability of Executive Order 14192 and finds this

action to be neither an E.O. 14192 regulatory action nor an E.O. 14192 deregulatory action.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 190.6 and found in the guidance have been approved under OMB control number 0910–0330.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21453 Filed 10–19–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Health Center Program Forms—OMB No. 0915–0285—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 19, 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 Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Program Forms, OMB No. 0915–0285—Revision

Abstract: The Health Center Program, administered by HRSA, is authorized under Section 330 of the Public Health Service Act (42 U.S.C. 254b). Health centers are patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients and adjust fees based on income and family size. More than 1,400 health centers operate nearly 17,000 service delivery sites that provide primary health care to more than 32 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA uses forms for new and existing health centers and other entities to apply for various grant and non-grant opportunities, renew grant and non-grant designations, report progress, and change their scopes of project.

A 60-day notice published in the **Federal Register** on July 30, 2026, Vol. 91, No.145, pp. 48170–72. There were no public comments.

Need and Proposed Use of the Information: The information HRSA collects from health centers via the Health Center Program-specific forms is necessary for the agency's oversight of Health Center Program awards. HRSA uses the information for program monitoring and for evaluating award recipients' compliance with Health Center Program statutory and regulatory requirements. These forms were approved by OMB on May 31, 2026, following 60- and 30-day public comment periods. Eight forms that were previously approved are being updated and three forms are being added to facilitate monitoring, improve scope of project documentation and oversight, increase the efficiency of the change in scope process, and enhance the accuracy of change in scope requests.

HRSA will modify the following forms to update and clarify data currently being collected:

Forms proposed to be modified: No./name	Description of modifications
Form 5A: Services Provided	Update labels and categories of services.
Form 5B: Sites	Modify fields collecting site information.
Checklist for Form 5A Scope Adjustments	Revise checklist statements and questions.
Checklist for Form 5B Scope Adjustments	Revise checklist statements and questions.
Checklist for Deleting a Service Site from Scope <i>Previously: Checklist for Deleting Existing Service Delivery Site.</i>	Revise checklist statements and questions.
Checklist for Adding a Service Site to Scope <i>Previously: Checklist for Adding a New Service Delivery Site.</i>	Revise checklist statements and questions.
Checklist for Adding a Service to Scope <i>Previously Checklist for adding a new service.</i>	Revise checklist statements and questions.
Checklist for Deleting a Service from Scope <i>Previously: Checklist for deleting existing service.</i>	Revise checklist statements and questions.

HRSA will add the following forms necessary for data collection and change in scope requests to simplify the process:

- Checklist for Replacing a Service Site in Scope: Checklist for updating a health center's scope to replace a service site.

- Quality Improvement Fund (QIF) Final Report: Collects data on the award recipient's QIF project progress as directed by the notice of funding opportunity.

- Loan Guarantee Progress Report: Used to monitor the status of the loan after the guarantee is issued to ensure the health center is compliant in meeting the terms and payment of the loan in the post monitoring phase of the program.

Likely Respondents: Health Center Program award recipients (those funded under section 330 of the Public Health

Service Act) and Health Center Program look-alikes.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

These updates will reduce the estimated annual burden by 1,621 hours based on the underlying unrounded burden calculations for the currently approved collection. The reduction reflects modifications to existing forms and the correction of the burden table to exclude *Form 5C: Other Activities/ Locations*. Form 5C was removed from the package during revisions completed earlier in 2026 and was inadvertently retained in the published 60-day **Federal Register** notice burden table. Compared with the 60-day notice, excluding Form 5C reduces the totals by 550 respondents, 550 responses, and 137.50 burden hours. In the burden table below, new forms are indicated through bold text, and revised forms are indicated through italicized text. Except for the correction regarding Form 5C described above, all other forms are unchanged.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form title	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Form 5A: Services Provided	1,400	1	1400	0.25	350.00
Form 5B: Sites	1,400	1	1400	0.25	350.00
Checklist for Form 5A Scope Adjustments	1,000	1	1000	1.00	1,000.00
Checklist for Form 5B Scope Adjustments	2,000	1	2000	1.00	2,000.00
Checklist for Deleting a Service Site from Scope <i>Previously: Checklist for Deleting Existing Service Delivery Site</i>	500	1	500	1.00	500.00
Checklist for Adding a Service Site to Scope <i>Previously: Checklist for Adding a New Service Delivery Site</i>	1,250	1	1250	1.50	1,875.00
Checklist for Adding a Service to Scope <i>Previously: Checklist for adding a new service</i>	450	1	450	1.00	450.00
Checklist for Deleting a Service from Scope <i>Previously: Checklist for deleting existing service</i>	500	1	500	1.00	500.00
Checklist for Replacing a Service Site in Scope	250	1	250	0.75	187.50
QIF Final Report	25	1	25	3.00	75.00
Loan Guarantee Progress Report	22	4	88	1.00	88.00
Capital Semi-Annual Progress Report	500	2	1,000	1.00	1,000.00
Equipment List	130	1	130	0.50	65.00
Federal Object Class Categories Form	500	1	500	0.25	125.00
Loan Guarantee Program Financial Performance Indicators	5	1	5	1.00	5.00

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form title	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Form 1A: General Information Worksheet	1,370	1	1,370	0.75	1,027.50
Form 1B: Funding Request Summary	900	1	900	0.75	675.00
Form 1C: Documents on File	1,460	1	1,460	0.50	730.00
Form 2: Staffing Profile	1,370	1	1,370	1.00	1,370.00
Form 3: Income Analysis	1,370	1	1,370	1.00	1,370.00
Form 6A: Current Board Member Characteristics	1,370	1	1,370	1.00	1,370.00
Form 6B: Request for Waiver of Board Member Requirements	1,370	1	1,370	1.00	1,370.00
Form 8: Health Center Agreements	1,370	1	1,370	1.00	1,370.00
Form 12: Organization Contacts	970	1	970	0.50	485.00
Funding Sources	130	1	130	0.50	65.00
FY 2022 Accelerating Cancer Screening Progress Report	29	1	29	1.50	43.50
Grant Number Form	400	1	400	0.25	100.00
Health Center Controlled Network Progress Report	50	1	50	0.50	25.00
Health Center Program Progress Report	130	1	130	1.00	130.00
HRSA Loan Guarantee Program Application	5	1	5	1.00	5.00
Impact Form	400	1	400	1.00	400.00
Native Hawaiian Health Care Improvement Act (NHHCIA) Non-Competing Continuation (NCC) Clinical Performance Measures	5	1	5	1.50	7.50
NHHCIA NCC Financial Performance Measures	5	1	5	0.50	2.50
NHHCIA NCC Income Analysis Form	5	1	5	0.15	0.75
NHHCIA Sample Project Work Plan	2	1	2	0.15	0.30
Native Hawaiian-NCC Project Work Plan Update	5	1	5	1.00	5.00
Operational Plan	350	1	350	2.00	700.00
Other Requirements for Sites	130	1	130	0.50	65.00
Participating Health Centers List	90	1	90	1.00	90.00
Project Cover Page	130	1	130	1.00	130.00
Project Narrative Update	1,325	1	1,325	4.00	5,300.00
Project Overview Form	500	1	500	1.00	500.00
Project Qualification Criteria	130	1	130	0.50	65.00
Project Work Plan	508	1	508	4.00	2,032.00
Proposal Cover Page	130	1	130	1.00	130.00
QIF Evaluative Measures Report	25	2	50	1.50	75.00
QIF Progress Report	25	12	300	1.50	450.00
QIF Transitions in Care for Justice-Involved Populations Evaluative Measures Report	54	10	540	1.50	810.00
QIF Transitions in Care for Justice-Involved Populations Progress Report	54	10	540	1.50	810.00
QIF Project Plan Form	100	1	100	1.00	100.00
Summary Page (New Access Point)	500	1	500	1.00	500.00
Summary Page (Service Area Competition)	360	1	360	0.50	180.00
Look-Alike Cover page	110	1	110	0.50	55.00
Checklist for Adding a Transitional Care in a Carceral Setting Site to Scope	50	1	50	1.00	50.00
Totals	27,219.00		29,057.00		31,164.55

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026-21385 Filed 10-19-26; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Partially Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Advisory Board.

The meeting will be partially open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or

other reasonable accommodation, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The intramural programs and projects and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the intramural programs and projects,

the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Date: December 2, 2026.

Open: 9:30 a.m. to 11:40 a.m.

Agenda: National Cancer Advisory Board Subcommittee Meetings.

Open: 12:00 p.m. to 4:00 p.m.

Agenda: Director's and program reports, presentations, and Board business.

Closed: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate the intramural program, site visit outcomes, and discussions of confidential personnel issues.

Address: National Institutes of Health, National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850.

Meeting Format: Virtual Meeting.

Contact Person: Shamala K. Srinivas, Ph.D., Acting Director, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Room 7W444, Bethesda, MD 20892, 240–276–6340, shamala@mail.nih.gov.

Registration is not required to attend the open portion of this meeting.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Persons listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's Advisory Board's web page on <https://www.cancer.gov/about-nci/advisory-boards/ncab/meetings/2026#december-1-2-2026-173rd-regular-meeting>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: October 15, 2026.

Kuleni D. Onnen,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–21401 Filed 10–19–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as

amended, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: January 20, 2027.

Open: January 20, 2027, 1:00 p.m. to 1:45 p.m. EST.

Agenda: Call to order; Announcements; Consideration of Summary Minutes for October 2026 Council, Future Council Dates; Working Group Updates; Concept Clearance.

Address: National Institutes of Health, NIDDK, 6707 Democracy Boulevard, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Closed: January 20, 2027, 2:00 p.m. to 3:00 p.m. EST.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, NIDDK, 6707 Democracy Boulevard, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, malikk@niddk.nih.gov.

Registration is not required to attend this meeting.

Information is also available on the Institute's/Center's home page: <https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: October 15, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–21396 Filed 10–19–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the President's Cancer Panel.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed by registering at the following link: <https://cbit.webex.com/webappng/sites/cbit/webinar/webinarSeries/register/0f90cb4edafdc4698998c75e91cb10fc4>.

Name of Committee: President's Cancer Panel.

Date: November 5, 2026.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Opportunities to Reduce Cancer Risk Through Nutrition: Roles for Industry and Government.

Address: National Institutes of Health 31 Center Drive, Room 11A30B, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Access to Meeting: <https://prescancerpanel.cancer.gov/reports-meetings/prevention-opportunities/nutrition-industry-government>.

Contact Person: Samantha L. Finstad, Ph.D., Executive Secretary, President's Cancer Panel, Office of the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A30B, MSC 2590, Bethesda, MD 20892, 240–276–6460, samantha.finstad@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the PCP website <https://prescancerpanel.cancer.gov/>, where an agenda, instructions for accessing the virtual meeting, and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer

Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: October 15, 2026.

Kuleni D. Onnen,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–21403 Filed 10–19–26; 8:45 am]

BILLING CODE 4167–05–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: Population Sciences and Epidemiology Integrated Review Group; Lifestyle and Health Behaviors Study Section.

Date: November 17–18, 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: Jewel L. Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–9038, jewel.wright@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell and Molecular Biology.

Date: November 17–18, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Kaitlyn N. Hardell, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3328, kaitlyn.hardell@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small

Business: Social and Behavioral Approaches to Promote Child and Family Health.

Date: November 17–18, 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: David E. Pollio, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1006F, Bethesda, MD 20892, (301) 594–4002, polliode@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training: Immunology and Infectious Diseases.

Date: November 17, 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: Thomas F. Conway, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 594–9085, chiuc@mail.nih.gov.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; HIV Molecular Virology, Cell Biology, and Drug Development Study Section.

Date: November 17, 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: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 808–A, Bethesda, MD 20892, (301) 827–3067, roebuckk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Immunology and Infectious Diseases.

Date: November 17–18, 2026.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lee G. Klinkenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–1706, lee.klinkenberg@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–26–121: Maximizing Investigators' Research Award.

Date: November 17–18, 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: Lauren Elizabeth Connell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 710K, Bethesda, MD 20892, (301) 480–3629, connelle@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Assay Development, Drug Discovery Tools and Imaging.

Date: November 17–18, 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: Angela Monique Boutte, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–0063, boutteam@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Computational, Modeling, and Biodata Management.

Date: November 17–18, 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: Archana Jha, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–5945, archana.jha@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mind Body and Integrative Health Treatment Approaches.

Date: November 17–18, 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: Cheryl K. Nordstrom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 809–N, Bethesda, MD 20892, (301) 594–6226, cheryl.nordstrom@nih.gov.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Advancing Therapeutics—B Study Section.

Date: November 17–18, 2026.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Heidi B. Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 907–H, Bethesda, MD 20892, (301) 827–3055, hfriedman@csr.nih.gov.
(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)
Dated: October 15, 2026.
Margaret N. Vardanian,
Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2026–21395 Filed 10–19–26; 8:45 am]
BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
National Cancer Institute; Notice of Meeting
Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the President’s Cancer Panel.
The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed by registering at the following link: <https://cbiit.webex.com/webappng/sites/cbiit/webinar/webinarSeries/register/0f90cb4edaf4698998c75e91cb10fc4>.
Name of Committee: President’s Cancer Panel.
Date: October 26, 2026.
Time: 12:00 p.m. to 5:00 p.m.
Agenda: Opportunities to Reduce Cancer Risk: Diet, Obesity, and Inflammation.
Address: National Institutes of Health 31 Center Drive, Room 11A30B Bethesda, MD 20892.

Meeting Format: Virtual Meeting.
Access to Meeting: <https://prescancerpanel.cancer.gov/reports-meetings/prevention-opportunities/diet-obesity-inflammation>.
Contact Person: Samantha L. Finstad, Ph.D., Executive Secretary, President’s Cancer Panel, Office of the Director, National Cancer Institute, NIH, 31 Center Drive, Room 11A30B, MSC 2590, Bethesda, MD 20892, 240–276–6460, samantha.finstad@nih.gov.
Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.
Information is also available on the PCP website <https://prescancerpanel.cancer.gov/>, where an agenda, instructions for accessing the virtual meeting, and any additional information for the meeting will be posted when available.
(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)
Dated: October 15, 2026.
Kuleni D. Onnen,
Program Analyst, Office of Federal Advisory Committee Policy.
[FR Doc. 2026–21402 Filed 10–19–26; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection
Accreditation of SGS North America, Inc. (Reserve, LA), as a Commercial Laboratory
AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.
ACTION: Notice of accreditation of SGS North America, Inc. (Reserve, LA), as a commercial laboratory.
SUMMARY: Notice is hereby given, pursuant to CBP regulations, that SGS North America, Inc. (Reserve, LA), has been accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of May 28, 2025.
DATES: SGS North America, Inc. (Reserve, LA), was accredited as a commercial laboratory as of May 28, 2025. The next triennial inspection date will be scheduled for May 2028.
FOR FURTHER INFORMATION CONTACT: Robert Harvey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW, Suite 1501A North, Washington, DC 20004, tel. 202–344–1060.
SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12, that SGS North America, Inc., 3735 W Airline Highway, Reserve, Louisiana 70084, has been accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12.
SGS North America, Inc. (Reserve, LA), is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.

Anyone wishing to employ this entity to conduct laboratory analyses should request and receive written assurances from the entity that it is accredited by the U.S. Customs and Border Protection to conduct the specific test requested. Alternatively, inquiries regarding the specific test this entity is accredited to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to CBPGaugersLabs@cbp.dhs.gov. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://>

www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.

Patricia A. Coleman,

Acting Assistant Commissioner, Laboratories and Scientific Services.

[FR Doc. 2026–21408 Filed 10–19–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc. (Carteret, NJ), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc. (Carteret, NJ), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that SGS

North America, Inc. (Carteret, NJ), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 5, 2025.

DATES: SGS North America, Inc. (Carteret, NJ) was approved and accredited as a commercial gauger and laboratory as of September 5, 2025. The next triennial inspection date will be scheduled for September 2028.

FOR FURTHER INFORMATION CONTACT:

Robert Harvey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW, Suite 1501A North, Washington, DC 20004, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that SGS North America, Inc., 900 Milik Street, Carteret, NJ 07008, has been approved to gauge petroleum and certain petroleum products and accredited to test

petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

SGS North America, Inc. (Carteret, NJ), is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API Chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculation of Petroleum Quantities.
17	Marine Measurement.

SGS North America, Inc. (Carteret, NJ), is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester.
27–57	D7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products and Liquid Fuels (Mini Method).
N/A	D1160	Standard Test Method for Distillation of Petroleum Products at Reduced Pressure.
N/A	D1319	Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to CBPGaugersLabs@cbp.dhs.gov. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. [http://www.cbp.gov/about/labs-](http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories)

[scientific/commercial-gaugers-and-laboratories](http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories).

Patricia A. Coleman,

Acting Assistant Commissioner, Laboratories and Scientific Services.

[FR Doc. 2026–21407 Filed 10–19–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc. (St. Rose, LA), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc. (St. Rose, LA), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that SGS North America, Inc. (St. Rose, LA), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of May 29, 2025.

DATES: SGS North America, Inc. (St. Rose, LA) was approved and accredited as a commercial gauger and laboratory as of May 29, 2025. The next triennial inspection date will be scheduled for May 2028.

FOR FURTHER INFORMATION CONTACT: Robert Harvey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue NW, Suite 1501A North, Washington, DC 20004, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that SGS North America, Inc., 151 James Drive West, St. Rose, LA 70087, has been approved to gauge petroleum and certain petroleum products and accredited to test

petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. SGS North America, Inc. (St. Rose, LA), is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
5	Metering.
7	Temperature Determination.
8	Sampling.

API chapters	Title
12	Calculation of Petroleum Quantities.
17	Marine Measurement.

SGS North America, Inc. (St. Rose, LA), is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for Density, Relative Density, and API Gravity of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.
27–53	D2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products and Liquid Fuels (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to CBPGaugersLabs@cbp.dhs.gov. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories>.

Patricia A. Coleman,
Acting Assistant Commissioner, Laboratories and Scientific Services.

[FR Doc. 2026–21405 Filed 10–19–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec, LLC (La Porte, TX), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec, LLC (La Porte, TX), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec, LLC (La Porte, TX), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of July 7, 2026.

DATES: AmSpec, LLC (La Porte, TX), was approved and accredited as a commercial gauger and laboratory as of July 7, 2026. The next inspection date will be scheduled for July 2029.

FOR FURTHER INFORMATION CONTACT: Dr. Justin Shey, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1331 Pennsylvania Avenue

NW, Suite 1501–A North, Washington, DC 20004, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that AmSpec, LLC, 1836 Miller Cut Off Road, La Porte, TX 77571, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

AmSpec, LLC (La Porte, TX), is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapters	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculation of Petroleum Quantities.
17	Marine Measurement.

AmSpec, LLC (La Porte, TX), is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory

Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27-03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27-04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27-06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27-11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27-13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27-48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.
27-50	D93	Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester.
27-54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method (Laboratory Procedure).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to CBPGaugersLabs@cbp.dhs.gov. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. <http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories>.

Patricia A. Coleman,
Acting Assistant Commissioner, Laboratories
and Scientific Services.

[FR Doc. 2026-21406 Filed 10-19-26; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

Fiscal Year 2026 Senior Executive Service Performance Review Boards

AGENCY: Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice announces the appointment of members of the Fiscal Year (FY) 2026 Senior Executive Service (SES) Performance Review Boards (PRBs) for the Department of Homeland Security (DHS). The purpose of the PRBs is to make recommendations to the appointing authority (*i.e.*, Agency Head) on the performance of senior executives (career and limited term appointees), including

recommendations on performance ratings, performance-based pay adjustments, and performance awards. The PRBs will also make recommendations on the performance of Transportation Security Executive Service, Senior-Level, and Scientific and Professional employees. To make its recommendations, the PRBs will review performance appraisals, initial summary ratings, any response by the employee, and any higher-level official's recommendation.

DATES: This Notice is applicable as of October 20, 2026.

FOR FURTHER INFORMATION CONTACT: Christian Fajardo, Human Resources Specialist, Office of the Chief Human Capital Officer, christian.fajardo@hq.dhs.gov, 771-200-0392.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c) and 5 CFR 430.311, each agency must establish one or more PRBs to make recommendations to the appointing authority (*i.e.*, Agency Head) on the performance of its senior executives. Each PRB must consist of three or more members. More than one-half of the membership of a PRB must be SES career appointees when reviewing appraisals and recommending performance-based pay adjustments or performance awards for career appointees. Composition of the PRB will be determined from among the individuals listed below:

List of Names (Alphabetical Order)

Alfonso-Royals, Angelica
Allende, Pedro
Anderson, Nicholas
Baker, Paul
Barrow, William Clark
Belcher, Brian
Blair Jr., Randolph
Brewer, Julie
Bright, Andrea

Brophy, Thomas
Browne, Rene
Carter, Ronald
Cavanaugh, Brian
Charles, Marcos
Condon, John
Cooch, Shila
Cooper, John
Corrado, Janene
Courtney, Paul
Curran, Sean
Daniels, Brent
Davis, Patrick
DiOrio, Christy
Donaghey, Rosanna
Donahue, James
Dorr, Robert
Dunbar, Susan
Eagan, Matthew
Eddy, Joseph
Edwards, Roland
Fenton, Jennifer
Fontenot, Kristin
Fosse, Charles
Fox, Katherine
Froemling, Hao-Y
Furey, Timothy
Gountanis, John
Harris, Melvin
Harrison, Kimberly
Hickey, Jonathan
Hoffman, Erin
Holland, Peter
Holmes, Lauren
Holtzer, Christopher
Huffman, Benjamin
Jackson, Jeffrey
Jackson, Kateland
Jankowski, Roman
Japak, Michelle
Jones, Keith
Judson, Paul
Kernoachan, James
Kessmeier, Jon
Khan, Rana
Kozma, Matthew
Kraft, Christopher
Law, Robert
Layou, Thomas

Lorincz, Csaba
Luke, Adam
Mandryck, James
Maykovich, Vincent
McCleary, Stephen
McCord, Antoine
McQuiston, Tyler
Mehringer, Holly
Mellendick, Theresa
Millhollin, Matt
Moline, Julia
Morgan-Rottman, Michal
Muehlenbeck, Todd
Murdock, Judson
Navarro, Mischell
Nelson, Jason
Noreiga, Katie
Olszewski, Nicholas
Pemberton, David
Percival, James
Pichon, Leslie
Quinn, Matthew
Regan, Thomas
Rezmovic, Jeffrey
Rief, Meghan
Roddini, Ariana
Roncone, Stephen
Sabatino, Diane
Scallan III, Joseph
Schneider, Jason
Schwink, John
Selby, Cara
Serrano-Glassner, Christine
Sharrett, Cary
Sinclair, Jennifer
Stahl, James
Stiefel, Nathaniel
Tashiro, Susan
Tomney, Christopher
Toms, Christopher
Walker Hall, Delisa

Wall, Charles
Watkins, Tracey
Wilson, Miltom
Windham, Nicole
Yeager, Chris
Yee, Britton

Dated: October 15, 2026.

Gregory Ruocco,

*Director, Executive Resources, Office of the
Chief Human Capital Officer.*

[FR Doc. 2026–21429 Filed 10–19–26; 8:45 am]

BILLING CODE 9112-FCM-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2026–0628]

Notice of Order Regarding Exclusion and Removal of DeepSeek Products From Federal Civilian Executive Branch Information Technology Systems and Procurements

AGENCY: Department of Homeland
Security (DHS).

ACTION: Notice of order.

SUMMARY: The Department of Homeland Security is publishing notice of the Secretary of Homeland Security's issuance of an order (1) excluding information technology products and services developed by Hangzhou DeepSeek Artificial Intelligence Co., Ltd (DeepSeek), to include affiliated entities as defined in applicable regulations, from federal civilian agency procurements; and, (2) removing all DeepSeek and DeepSeek-affiliate products, and third-party products and

services developed using DeepSeek implementations, from civilian agency information technology.

FOR FURTHER INFORMATION CONTACT:

FASCSA Order Implementation Team
CISA Cybersecurity Division,
fascsa.orders@cisa.dhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted by the Federal Acquisition Supply Chain Security Act of 2018, 41 U.S.C. 1321–1328, and implementing regulations at 41 CFR 201–1, following review of the Federal Acquisition Security Council Recommendation and affiliated evidence, the Secretary of Homeland Security has ordered: (1) exclusion of information technology products and services developed by Hangzhou DeepSeek Artificial Intelligence Co., Ltd (DeepSeek), to include affiliated entities as defined in 48 CFR 2.101, from federal civilian agency procurements; and (2) removal of all DeepSeek and DeepSeek-affiliate products, and third-party products and services developed using DeepSeek implementations, from civilian agency information technology.

A copy of the signed order is contained in the accompanying Appendix and can be found at <https://www.regulations.gov> by searching for DHS Docket Number DHS–2026–0628.

James H. Percival II,

*General Counsel, U.S. Department of
Homeland Security.*

Appendix

BILLING CODE 9111-LF-P

Exclusion and Removal Order #2026-01**Federal Acquisition Supply Chain Security Act Exclusion and Removal of DeepSeek Products and Services from Federal Civilian Executive Branch Information Technology Systems**

Original Release Date: July 24, 2026

Applies To: Federal Civilian Executive Branch Agencies except for their national security systems and secure compartmented information systems

FROM: Markwayne Mullin 
Secretary, Department of Homeland Security

CC: Russell Vought
Director, Office of Management and Budget

The Federal Acquisition Supply Chain Security Act of 2018, 41 U.S.C. §§ 1321-1328, and implementing regulations at 41 C.F.R. part 201-1, authorize the Secretary of Homeland Security to issue exclusion and/or removal orders for purposes of safeguarding federal civilian information systems. Recommendations of the Council shall be reviewed by the Secretary of Homeland Security, who may issue exclusion and removal orders based upon such recommendations, to the extent not covered by the Department of Defense [Department of War] or the Intelligence Community. 41 U.S.C. §1323 (c)(5)(A). Section 201-1.304 of the Federal Acquisition Supply Chain Security Act Final Rule states that executive agencies shall comply with exclusion and removal orders issued pursuant to § 201-1.303.

Background:

Information and communications technology are vital to U.S. government systems. The Federal Acquisition Supply Chain Security Act of 2018 created the Federal Acquisition Security Council (FASC) to manage supply chain risks by recommending exclusion or removal of risky products or services from federal procurement and IT systems. The Secretary of Homeland Security can issue exclusion or removal orders for Federal civilian agency systems, except those under the Department of War and the Office of the Director of National Intelligence.

Summary of Risks from Source:

Hangzhou DeepSeek Artificial Intelligence Basic Technology Research Co., Ltd. (hereinafter DeepSeek), a foreign, privately-owned company, located in the People's Republic of China¹ (PRC) provides multiple artificial intelligence applications available widely and free of charge.² DeepSeek's models present multiple threat vectors. DeepSeek servers are located in the PRC.³

¹ "Hangzhou DeepSeek Artificial Intelligence Basic Technology Research Company Profile." *exovera.com*, January 31, 2025, https://exovera.com/wp-content/uploads/2025/02/DeepSeek_Profile_2025_01_31-Final.pdf.

² "DeepSeek explained: Everything you need to know." *TechTarget*, August 25, 2025, <https://www.techtarget.com/WhatIs/feature/DeepSeek-explained-Everything-you-need-to-know>.

³ DeepSeek's Privacy Policy, available at <https://web.archive.org/web/20250306100653/https://cdn.deepseek.com/policies/en-US/deepseek-privacy-policy.html>; Charles Mok. "Taking Stock of the DeepSeek Shock." *Stanford Cyber Policy Center*, February 5, 2025, <https://cyber.fsi.stanford.edu/publication/taking-stock-deepseek-shock>.

and the PRC legal system permits extensive authority to government cyber and intelligence functions to access private company infrastructure.⁴ For DeepSeek-hosted instances of their models, DeepSeek's account generation process collects personally identifiable information (PII) and may also track and digitally fingerprint users.⁵ DeepSeek's most widely used applications function through a prompt-and-response process that requires presenting information to the model, and which may result in the transfer of sensitive data to the PRC if used by U.S. government employees or vendors.⁶ The transfer of the aforementioned information to the PRC, either independently or in combination with publicly available data, could produce actionable intelligence on U.S. persons and/or government programs. The models themselves may contain malware or other security vulnerabilities. Indeed, open-source security research has found that the DeepSeek iOS mobile application contains multiple critical vulnerabilities.⁷

Scope:

This Exclusion and Removal Order direct Federal civilian agencies⁸ to: (1) **exclude** DeepSeek, DeepSeek-affiliated entities⁹, and their products from civilian agency procurements,¹⁰ and (2) **remove** products provided by DeepSeek and DeepSeek entities, and third-party products and services developed using DeepSeek implementations, from civilian agency information technology systems.¹¹

⁴ "Data Security Business Advisory: Risks and Considerations for Businesses Using data services and equipment from firms linked to the PRC." Department of Homeland Security, December 22, 2020. https://www.dhs.gov/sites/default/files/publications/20_1222_data-security-business-advisory.pdf.

⁵ DeepSeek's Privacy Policy, p. 2 is available at <https://web.archive.org/web/20250306100653/https://cdn.deepseek.com/policies/en-US/deepseek-privacy-policy.html>; *DeepSeek Unmasked: Exposing the CCP's Latest Tool for Spying, Stealing, and Subverting U.S. Export Control Restrictions*. The Select Committee on the Strategic Competition Between the United States and the Chinese Communist Party, April 16, 2025, pp. 3 and n.13 and 14, <https://selectcommitteeontheccp.house.gov/sites/evo-subsites/selectcommitteeontheccp.house.gov/files/evo-media-document/DeepSeek%20Final.pdf>.

⁶ DeepSeek's Privacy Policy, p. 2 is available at <https://web.archive.org/web/20250306100653/https://cdn.deepseek.com/policies/en-US/deepseek-privacy-policy.html>.

⁷ Andrew Hoog, "NowSecure Uncovers Multiple Security and Privacy Flaws in DeepSeek iOS Mobile App." *NowSecure*, February 6, 2025. <https://www.nowsecure.com/blog/2025/02/06/nowsecure-uncovers-multiple-security-and-privacy-flaws-in-deepseek-ios-mobile-app/>

⁸ The Secretary of Homeland Security's authority to issue exclusion and removal orders is applicable to civilian agencies, to the extent not covered by the authority of the Secretary of Defense and Director of National Intelligence, as defined by 41 U.S.C. § 1323(5)(A)(ii) or (iii).

(ii) The Secretary of Defense, for exclusion and removal orders applicable to the Department of Defense and national security systems other than sensitive compartmented information systems.

(iii) The Director of National Intelligence, for exclusion and removal orders applicable to the intelligence community and sensitive compartmented information systems, to the extent not covered by clause (ii).

⁹ For purposes of this Order, an individual or business is an "affiliated entity" or "affiliate" of DeepSeek AG if, directly or indirectly, either one controls or can control the other; or a third party controls or can control both. See 48 C.F.R. § 2.101 (definition of "affiliates").

¹⁰ To include third party implementations of DeepSeek used to provide products and services civilian agencies.

¹¹ Pursuant to 41 U.S.C. § 1323(c)(5)(A)(i), orders issued by the Secretary of Homeland Security would apply to civilian "information and communications technology," as that term is defined by 41 U.S.C. § 1321(5).

Required Actions:

All civilian agencies are required to:

1. **Exclude** DeepSeek, DeepSeek-affiliated entities,¹² and their products from civilian agency procurements,¹³ effective immediately after issuance of this Order, to include agency-approved products lists, service provider equipment lists, e-commerce markets, and other similar functions that facilitate the procurement of information technology hardware, software, and services.
2. **Remove products provided by** DeepSeek, DeepSeek-affiliated entities, and third-party products and services developed using DeepSeek implementations, from civilian agency information technology systems¹⁴ immediately after the issuance of the Order, or seek an Exception, as described below.

Exceptions:

Executive agencies may request an exception from the DHS Issuing Official under 41 C.F.R. § 201-1.304(b), such as asking that the order not apply to the agency, certain actions, or for a delay in compliance.

Executive agency requests for exceptions must be **submitted in writing within 60 days** of the issuance of this order and include all necessary information for the issuing official to review and evaluate it, including:

1. Identification of the applicable exclusion order or removal order;
2. A description of the exception sought, including, if limited to only a portion of the order, a description of the order provisions from which an exception is sought;
3. The name or a description sufficient to identify the covered article or the product or service provided by a source that is subject to the order from which an exception is sought;
4. Compelling justification for why an exception should be granted, such as the impact of the order on the agency's ability to fulfill its mission-critical functions, or considerations related to the national interest, including national security reviews, national security investigations, or national security agreements; and
5. Any alternative mitigations to be undertaken to reduce the risks addressed by the exclusion or removal order.

CISA will review requests for exceptions and provide a written approval or disapproval. Please submit any exception requests to FASCSA.Orders@cisa.dhs.gov.

Interim Cybersecurity Measures:

¹² For purposes of this Order, an individual or business is an "affiliated entity" or "affiliate" of DeepSeek AG if, directly or indirectly, either one controls or can control the other; or a third party controls or can control both. See 48 C.F.R. § 2.101 (definition of "affiliates").

¹³ To include third party implementations of DeepSeek used to provide products and services to civilian agencies.

¹⁴ Pursuant to 41 U.S.C. § 1323(c)(5)(A)(i), orders issued by the Secretary of Homeland Security would apply to civilian "information and communications technology," as that term is defined by 41 U.S.C. § 1321(5).

During the period between the issuance of this order and full removal of covered articles from agency systems, federal agencies are encouraged to take steps to address risks to their systems, such as monitoring the flow of traffic in and out of the agency, implementing enhanced logging and controls on data exfiltration for the relevant systems, and detecting and flagging anomalous activity.

Actions by DHS and its Cybersecurity and Infrastructure Security Agency (CISA):

1. CISA may provide technical assistance to agencies that are without internal capabilities sufficient to comply with this Order.
2. DHS will review requests for exceptions and provide written approval or disapproval for the department.
3. The Secretary of Homeland Security will review this order as required by the Federal Acquisition Supply Chain Security Act within one year and annually thereafter.

Additional Information:

Contact FASCSA.Orders@cisa.dhs.gov for additional information, assistance, and reporting.

**DEPARTMENT OF HOUSING AND
URBAN DEVELOPMENT**

[Docket No. FR-7103-N-10; OMB Control
No.: 2528-0346]

**60-Day Notice of Proposed Information
Collection: Exhibitors Sought for the
Innovative Housing Showcase**

AGENCY: Office of the Assistant
Secretary for Policy Development and
Research, Department of HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 21, 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: Jagruti Rekhi, Social Science Analyst, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410. Comments may also be submitted via email to PDRPublicComments@hud.gov.

FOR FURTHER INFORMATION CONTACT: Jagruti Rekhi, Social Science Analyst, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, email: Jagruti.D.Rekhi@hud.gov or telephone (202) 402-4512. 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. Rekhi.

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: Data Collection for HUD's Innovative Housing Showcase

OMB Approval Number: 2528-0346.

Type of Request: Revision.

Form Number: N/A.

Description of the need for the information and proposed use: The Innovative Housing Showcase (IHS) is a public event to raise awareness of new, innovative housing technologies, especially offsite constructed or factory-built housing. HUD is seeking potential exhibitors who have developed innovative housing technologies to show their technologies to the public.

HUD seeks to collect information to identify exhibitors for the Innovative Housing Showcase (Showcase) and obtain information from exhibitors after the Showcase. Exhibitors provide key information about their products, allowing HUD to review and make informed decisions on this innovation

to accept. The application form streamlines information collection by focusing on information required to vet the specific product that will be exhibited. The changes are a revision per the addition of a post-exhibit questionnaire. This new questionnaire solicits information from exhibitors on how to improve future showcases and how HUD can make the event more valuable for their company. It will not collect sensitive or proprietary information.

Respondents: Product manufacturers, innovators, and construction industry stakeholders.

Estimated Number of Respondents: 100.

Estimated Number of Responses: 160 (100 applicants and 60 responses are exhibitors who complete the exit interview after the end of the Showcase).

Frequency of Response: 2.

Average Hours per Response: 3 hours for application and .5 hours for the exit interview.

Total Estimated Burdens: The cost to respondents to complete an application is estimated at the marketing manager's median hourly wage rate (\$79.70) for 3 hours of work. The total estimated cost is \$26,301 (\$23,910 + \$2,391).

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Innovative Housing Showcase	100	1	100	3	300	\$79.70	\$23,910
Exit Interview	60	1	60	.5	30	79.70	2,391

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 comments in response to these questions.

C. Authority

44 U.S.C. 3507.

Todd M. Richardson,

General Deputy Assistant Secretary for Policy Development and Research.

[FR Doc. 2026-21451 Filed 10-19-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7110-N-19; OMB Control No.: 2502-0419]

60-Day Notice of Proposed Information Collection: Application for Insurance Benefits

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 21, 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: Darian Ziegler, PRA Liaison,

Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Darian Ziegler, PRA Liaison, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Darian.Ziegler@hud.gov, telephone (202) 402–5535 (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. Ziegler.

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: Multifamily Mortgagee’s Application for Insurance Benefits.
OMB Approval Number: 2502–0419.
Type of Request: Extension of currently approved collection.
Form Number: Form HUD–2747, Application for Insurance Benefits, Multifamily Mortgage.
Description of the need for the information and proposed use: A lender

with an insured multifamily mortgage pays annual insurance premium to the Department. When and if the mortgage goes into default, the lender may elect to file a claim for insurance benefits with the Department. A requirement of the claims process is the submission of an application for insurance benefits. Form HUD–2747, Mortgagee’s Application for Insurance Benefits (Multifamily Mortgage), satisfies this requirement.

Respondents: Not-for-profit institutions, State, local or Tribal Government.

Estimated Number of Respondents: 110.
Estimated Number of Responses: 110.
Frequency of Response: Occasion.
Average Hours per Response: 1.
Total Estimated Burdens: 110.

Form HUD–2747	110	1	110	1	110	33.51	\$3,686.1
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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 comments in response to these questions.

C. Authority

44 U.S.C. 3507.

Paul M. Olin,
Acting General Deputy Assistant Secretary for Housing.
[FR Doc. 2026–21426 Filed 10–19–26; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management
[Docket No. BOEM–2026–0331]

American Samoa Outer Continental Shelf Pacific Mineral Lease Sale 1

AGENCY: Bureau of Ocean Energy Management, Interior.
ACTION: Final leasing notice.

SUMMARY: The Marine Minerals Administration (MMA) will conduct an auction for lease areas offered in the American Samoa Outer Continental Shelf (OCS) Pacific Mineral Lease Sale 1 (Lease Sale PACM–1), in accordance with the Outer Continental Shelf Lands Act (OCSLA), as amended, and its implementing regulations. The Final Leasing Notice (FLN) package for this lease sale contains information essential to potential bidders, including Information to Lessees and Lease Stipulations.

DATES: MMA will hold Lease Sale PACM–1 on Thursday, November 19, 2026, at 9:00 a.m. All times referred to in this document will be Pacific Time, unless otherwise specified. Lease areas will be awarded through an ascending oral auction. For more information on bid submission and auction rules, see Section VII of this document, “Bidding Instructions.”

ADDRESSES: Interested parties may download the FLN package, and associated maps, from MMA’s website at <https://www.boem.gov/marine-minerals/american-samoa-activities>. Copies of the FLN and sale maps can also be obtained by contacting the MMA

Pacific Regional Office at this address: Marine Minerals Administration, 760 Paseo Camarillo (CM 102), Camarillo, CA 93010, (805) 384–6305.

FOR FURTHER INFORMATION CONTACT: Joshua Gange, Supervisor for Leasing and Technical Review, Marine Minerals Administration, Pacific Region, 760 Paseo Camarillo, CA 93010, at Pacific.Region@boem.gov and (805) 384–6305.

SUPPLEMENTARY INFORMATION:

Authority: This sale will be held pursuant to the requirements of and is published pursuant to 43 U.S.C. 1331 *et seq.* (Outer Continental Shelf Lands Act, as amended) and 30 CFR part 581, subpart B—Leasing Procedures. Secretary’s Order 3451 established the Marine Minerals Administration (MMA), which replaced BOEM, and provided for a transition period during which existing MMA officials retain operational authority necessary for the uninterrupted accomplishment of its mission. That transition period is ongoing. Accordingly, this notice references both BOEM and MMA but is issued under the authority of the MMA.

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I. Lease Sale Area
II. Statutes and Regulations
III. Lease and Fiscal Terms
IV. Lease Stipulations
V. Information to Lessees
VI. Maps
VII. Bidding Instructions
VIII. The Lease Sale
IX. Bidding Rules
X. Delay of Sale

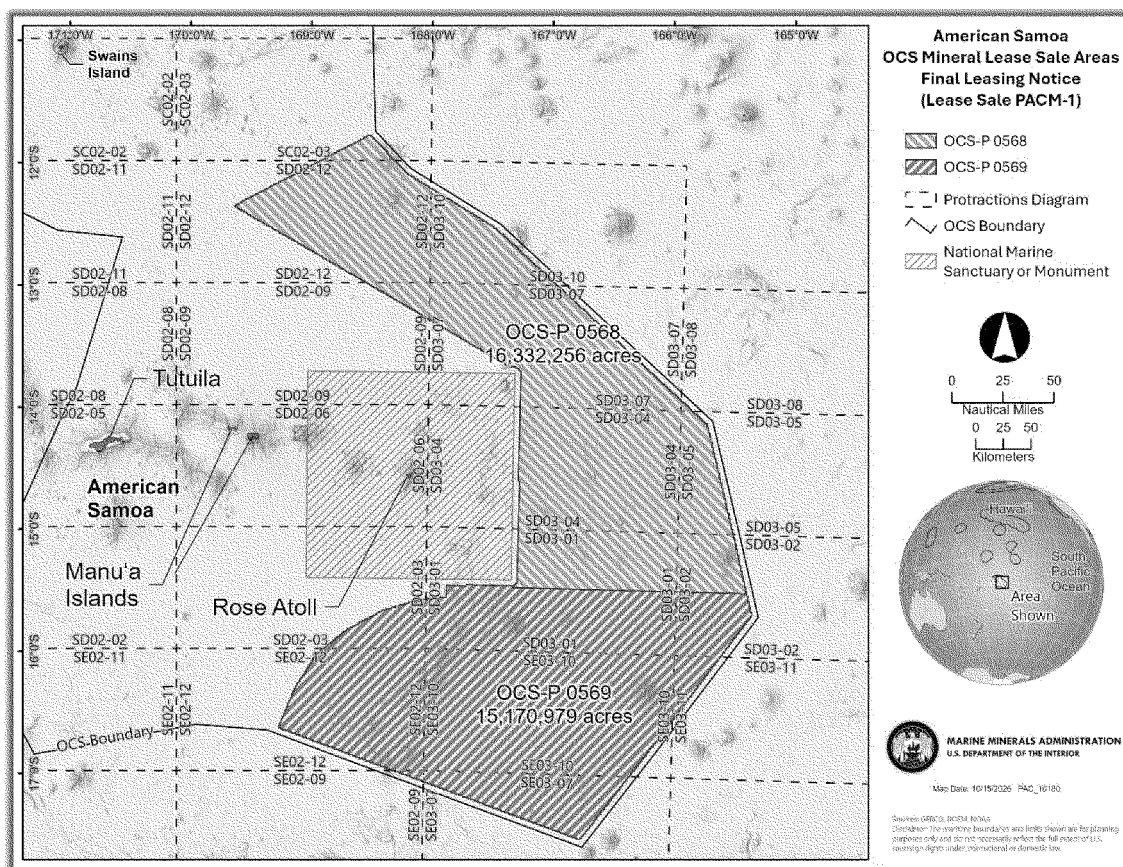
I. Lease Sale Area

MMA is offering for bid in Lease Sale PACM-1 all available unleased acreage as identified on the map entitled, "American Samoa OCS Mineral Lease

Sale Areas Final Leasing Notice (Lease Sale PACM-1)." Two individual lease areas have been identified; OCS-P 0568 is approximately 16,332,256 acres and OCS-P 0569 is approximately

15,170,979 acres. The final list of blocks available for bid is posted on MMA's website at <https://www.boem.gov/marine-minerals/american-samoa-activities>.

Figure 1: American Samoa OCS Mineral Lease Sale Areas Final Leasing Notice



MMA's Official Protraction Diagrams (OPDs) and Supplemental OPDs for the lease areas are available online at <https://www.boem.gov/pacific-cadastral-data>. All blocks are shown on the following OPDs:

Achilles Tang (SC02-03)
Hutchinson Seamount (SD02-03)
Small Toothed Jobfish (SD02-09)
Dusky Frillgoby (SD02-12)
Arrowhead Soapfish (SE02-09)
Flowery Flounder (SE02-12)
Slimy Cuskeel (SD03-01)
Honeycomb Toby (SD03-02)
Sixblotch Hind (SD03-04)
Sculptured Pipefish (SD03-05)
Paletail Chromis (SD03-07)
Mosaic Gulper Shark (SD03-08)
Clown Coris (SD03-10)
Knife Razorfish (SE03-07)
Dusky Sleeper (SE03-10)
Brokenbar Dwarfgoby (SE03-11)

II. Statutes and Regulations

Each lease is issued pursuant to OCSLA, 43 U.S.C. 1331 *et seq.*, as amended, and is subject to OCSLA's implementing regulations in 30 CFR part 581, and other applicable statutes and regulations in existence upon the effective date of the lease, as well as those applicable statutes enacted and regulations promulgated thereafter, except to the extent that the after-enacted statutes and regulations conflict with an express provision of the lease. Each lease is subject to amendments to statutes and regulations, including but not limited to OCSLA, that do not explicitly conflict with an express provision of the lease. The Lessee expressly bears the risk that such new or amended statutes and regulations (*i.e.*, those that do not conflict with an express provision of the lease) may

increase or decrease the Lessee's obligations under the lease.

The lease and fiscal terms, along with MMA's ascending oral auction format, will ensure that the United States receives fair market value (FMV) for each lease area offered. The auction winner will be provisionally awarded the lease (assuming the winner did not violate any rules), and final issuance of the executed lease will take place after the sale date as outlined in the section entitled, "Acceptance, Rejection, or Return of Bids."

III. Lease and Fiscal Terms

MMA is offering two lease areas for development of all marine minerals or metals found in polymetallic nodules and ferromanganese crust deposits discovered within the leased area. Any lease(s) that are issued will grant the Lessee(s) an opportunity to identify mineral deposits and seek approval to

develop these deposit types and minerals, as well as any minerals produced incidental to and in direct association with production from these deposits. All other minerals will be reserved from the lease(s) to the Lessor, including but not limited to oil, gas, sulphur, and source materials for fissionable materials, as required by 30 CFR 581.8.

OCS Lease Form

MMA proposes to use Form BOEM–2004 (April 2026) to convey leases resulting from this sale. This lease form can be viewed on MMA’s website at <https://www.boem.gov/about-boem/>

procurement-business-opportunities/boem-ocs-operation-forms. The lease form will be amended to include specific terms, conditions, and stipulations applicable to the individual lease. The terms, conditions, and stipulations applicable to this sale are described below.

The following section outlines the lease and fiscal terms for Lease Sale PACM–1.

Primary Term

The Primary Term will be 20 years.

Minimum Bonus Bid Amount

The minimum bonus bid amount will be \$3,000,000 for each lease area offered.

Rental Rates

Annual rental rates depend on the lease year and the relative percentage of the *Initial Lease Area* the Lessee continues to hold. The table below shows the applicable rent per acre for each lease year, based on whether the Lessee retains:

- Less than 15%,
- 15% to less than 50%, or
- 50% or more of the Initial Lease Area.

TABLE 1—RENTAL RATES PER ACRE

Lease year	Rent per acre if 0 to <15 percent of Initial Lease Area is retained	Rent per acre if 15 to <50 percent of Initial Lease Area is retained	Rent per acre if 50+ Percent of Initial Lease Area is retained
0–5 Years	\$0.00	\$0.00	\$0.00
6–10 Years	0.30	0.60	1.20
11–15 Years	1.25	2.50	5.00
16–20 Years	2.50	5.00	10.00

Rental payments will continue until the first lease anniversary date following the commencement of royalty payments on leasehold production (meaning production that occurs under the first approved Mining Plan).

Lease segregation does not change how much of the Initial Lease Area is considered retained. If a lease is subsequently segregated, acreage percentages of Initial Lease Area Retained will be recalculated based on the proportion of each new lease area to

the Initial Lease Area. For example, if a lease is segregated into two leases, one of which is 25% of the Initial Lease Area and the other is 75% of the Initial Lease Area, the 25% lease area would need to be relinquished down to <3.75% (15% * 25%) of the Initial Lease Area in order to pay the rental rates in the first column. In order to pay the middle rates, that same 25% lease area would need to be relinquished down to 3.75 to < 12.5%. The 75% lease area would need to be relinquished down to

11.25% (15% * 75%) of the Initial Lease Area to pay the rental rates in the first column.

Minimum Royalty Rate

The minimum royalty rate is locked in based on the lease year in which leasehold production (meaning production that occurs under the first approved Mining Plan) begins as well as the share of the Initial Lease Area held when production begins according to the following schedule:

TABLE 2—MINIMUM ROYALTY RATE

Mining plan production start year	Lease Area retained is less than 15% of Initial Lease Area?	Minimum royalty (per acre)
0–15 Years	Yes	\$1.25
0–15 Years	No	2.50
16–20 Years	Yes	2.50
16–20 Years	No	5.00

Royalty Rate

Royalty on Delineation and Testing:

The Lessee must pay to the Lessor a royalty of five percent on all mineral production under any approved Delineation or Testing Plan that is processed to a marketable condition or sold.

Initial Production Royalty Rate:

The Lessee must pay to the Lessor a royalty of two percent on the value of the mineral production, as described

below, from the lease during the first five years of production under any approved Mining Plan. The five-year period commences on the first of the month in which minerals are first produced on the lease under an approved Mining Plan.

Subsequent Production Royalty Rate:

Beginning on the first day of the sixth (6th) year of mineral production under an approved Mining Plan and continuing thereafter for the remainder

of the lease, the Lessee must pay to the Lessor a royalty of five percent on the value of the mineral production, as described below, from the lease.

TABLE 3—SUBSEQUENT PRODUCTION ROYALTY RATE

Mining plan production year	Royalty rate (%)
1–5	2

TABLE 3—SUBSEQUENT PRODUCTION ROYALTY RATE—Continued

Mining plan production year	Royalty rate (%)
6+	5

Valuation for Royalty Purposes

In accordance with regulations at 30 CFR part 1206, subpart G—Other Solid Minerals, the following terms, conditions, and stipulations will apply for royalty payments on the value of the mineral production from a lease.

Marketable Condition: Marketable condition means mineral production from the lease that is processed in a manner consistent with prevailing practices in the industry as determined by the Director of the Office of Natural Resources Revenue and otherwise in a condition that will be accepted by an arm's length purchaser under a sales contract typical for the commodity. Mineral production from the lease must meet the marketable condition requirement prior to being sold to be considered a bona fide transaction under 30 CFR part 1206, subpart G.

Allowances: A Lessee may claim the specific costs enumerated below as allowable deductions. Except as described below, no other deductions will be allowed. However, under no circumstances may the mineral production from the lease, minus allowances, be valued for royalty purposes less than the monthly average value of the free on board (f.o.b.) bulk sales price realized at the customary point of shipment to market.

Transportation: A deduction will be allowed for the Lessee's costs equal to the difference between the bona fide sale of mineral production from the lease in bulk for that sales month at the customary point of shipment to market and the sale price realized at a remote sales point.

Beneficiation Beyond Marketable Condition: A deduction will be allowed for the Lessee's costs equal to the difference between the bona fide sale of mineral production from the lease in bulk for that sales month at the customary point of shipment to market and the sale price realized for lease material processed to a condition considered beyond marketable condition.

Royalty Relief

No royalty relief will be offered in this sale.

IV. Lease Stipulations

Stipulations applied to leases issued in this sale are contained in the "Lease

Stipulations" section of the FLN package and cover the topics enumerated below.

1. Lease Preliminary Activities and Survey Notices
2. Endangered Species Act and Essential Fish Habitat Consultation Requirements
3. Fisheries Communication Plan
4. Protection of Birds
5. Marine Archaeology Requirements for Preliminary Activities
6. Unanticipated Discovery Requirements
7. Research Site Access
8. Preliminary Activities Reporting
9. Confidential Information
10. Community Investment and Economic Development
11. Local Content and Labor Utilization
12. Supply Chain Statement of Goals
13. Port Utilization and Infrastructure Investment

V. Information to Lessees

The Information to Lessees (ITLs) provide detailed information on certain issues pertaining to this lease sale. The full text of the ITLs for this sale is contained in the "Information to Lessees" section of the FLN package and covers the following topics:

1. Navigation Safety
2. Geological and Geophysical Surveys
3. Marine Archaeological Survey Requirements for Delineation, Testing, and Mining Plans
4. Environmental Monitoring
5. Mining Discharge Analysis
6. Data and Metadata Standards
7. Low-Impact Collector Technology Rationale
8. Community Engagement Plan
9. Dock Space
10. Notice of Assignment to the Committee on Foreign Investment in the United States (CFIUS)
11. Domestic Mineral Processing and Supply Chain
12. Engagement
13. Local Emergency Preparedness and Maritime Safety Support

VI. Maps

The American Samoa OCS Mineral Lease Sale Area Map can be viewed on MMA's website at <https://www.boem.gov/marine-minerals/american-samoa-activities>, including a more detailed map of the lease blocks and aliquots. The sale area is shown on the map entitled, "American Samoa OCS Mineral Lease Sale Areas Final Leasing Notice (Lease Sale PACM-1)."

VII. Bidding Instructions

Bidding instructions and the required format for the items are listed below. Bidders should refer to the subheading

entitled, "Acceptance, Rejection, or Return of Bids" under Section IX below, regarding a bidder's failure to comply with the requirements of this FLN, including failure to follow the instructions and format and timely submit the information required in this FLN.

Authorized Individuals and Bidder Authentication

An entity that is eligible to participate in the auction may identify up to five (5) individuals who will be authorized to bid on behalf of the company, including their names, business telephone numbers, and email addresses. Bidders are advised that MMA considers the Bidder's Financial Form (BFF) to be a legally binding obligation on the part of the bidder(s) to comply with all applicable regulations, including, but not limited to, the regulation requiring payment of bid deposit.

Affiliated Entities

On the BFF, eligible bidders must list any other entities with whom they are affiliated. For the purpose of identifying affiliated entities, a bidding entity is any individual, firm, corporation, association, partnership, consortium, or joint venture (when established as a separate entity) that is participating in the same auction. Affiliated entities are not permitted to compete against each other in the auction. Where two or more affiliated entities have qualified to bid in the auction, the affiliated entities must decide prior to the auction which one (if any) will participate in the auction. If two or more affiliated entities attempt to participate in the auction, MMA will disqualify those bidders from the auction.

MMA considers two entities to be affiliated if (a) one entity (or its parent or subsidiary) has or retains a right, title, or interest in the other entity (or its parent or subsidiary), including the ability to control or direct actions with respect to such entity, either directly or indirectly, individually or through any other party; or (b) the entities are both direct or indirect subsidiaries of the same parent company. Entities are also affiliated if ownership or common ownership of more than 50 percent of the voting securities, or instruments of ownership or other forms of ownership, of another person constitutes control (person means any individual, firm, corporation, association, partnership, consortium, or joint venture (when established as a separate entity)). MMA will consider each of the following factors to determine if there is control under the circumstances of a particular case:

- The extent to which there are common officers or directors.
- With respect to the voting securities, or instruments of ownership or other forms of ownership: The percentage of ownership or common ownership, the relative percentage of ownership or common ownership compared to the percentage(s) of ownership by other persons, if a person is the greatest single owner, or if there is an opposing voting bloc of greater ownership.
- Operation of a common lease, plant, pipeline, or other facility.
- The extent of other owners' participation in operations and day-to-day management of a lease, plant, or other facility.
- Other evidence of power to exercise control over or common control with another person.

Bidder's Financial Form

Each qualified bidder must submit a BFF to participate in the auction. A BFF must be received no later than October 29, 2026. Bidders are hereby notified that, on the day of the sale, an authorized representative must recertify the BFF, affirming that all information submitted on the BFF is accurate and remains valid in accordance with the requirements of 30 CFR 581.20. A copy of the form is available at <https://www.boem.gov/marine-minerals/critical-minerals/bidder-financial-formapril-2026>. In its BFF, each bidder must designate the email address that it will use to create an account in <https://www.pay.gov>. The BFF is required to be executed by an authorized representative listed in the bidder's qualification documents on file with MMA. The BFF must contain the following information:

- Each bidder's MMA qualification number. Bidders participating in this lease sale must be qualified by MMA pursuant to 30 CFR 581.4 and 30 CFR 581.20. Bidders seeking to participate in this lease sale who are not qualified by MMA should submit the required qualification documentation as early as possible to ensure there is sufficient time to receive a MMA qualification number. Bidders can submit the required qualification documents to pacific.region@boem.gov.
- A statement acknowledging that the bidder(s) understands that all oral bids legally bind the bidder(s) to comply with all applicable regulations, including, but not limited to, the requirement to pay the balance of the bonus bid amount for any lease area bid upon.
- Contact information, including names, addresses, telephone numbers,

and email addresses for the principal point of contact, payment and refund coordination, and up to five (5) individuals authorized to bid.

- Identification of any affiliated entities as defined above and confirmed in this FLN for this lease sale.
- Recertification of the information provided in the BFF on the day of the sale. Prior to the offering of any oral bids at the lease sale, an authorized representative must confirm that the *information provided by the company in the BFF remains accurate and the company's eligibility to participate in the lease sale is unchanged*. Any updates or changes must be declared at this time. Bidders who do not complete the required recertification will not be permitted to submit an oral bid.

For this sale, MMA will only accept bidders' BFFs by mail. Instructions for submission can be found on the BFF. The BFF must be executed on paper with a signature by an authorized representative identified in the bidder's qualification documentation as authorized to bind the company.

VIII. The Lease Sale

Auction Format

Location: MMA will hold Lease Sale PACM-1 on Thursday, November 19, 2026, at 9:00 a.m., at the Ventura County Fire Department Headquarters, 2400 Conejo Spectrum Street, Thousand Oaks, CA 91320. The venue will not be open to the public. Only qualified bidders and their designated representatives will be admitted to the venue. The oral ascending clock auction will be live streamed on MMA's website at <https://www.boem.gov> for public viewing.

Time Zone: All times referenced in this document are Pacific Time, unless otherwise specified.

Purpose: The oral auction is solely for taking oral bids from qualified bidders until only one bidder remains on each lease area. MMA will announce a provisional winner for each lease area at the conclusion of the auction. The United States reserves the right to reject any and all bids, as detailed in Section IX of this document under the subheading entitled, "Acceptance, Rejection, or Return of Bids" below.

Auction Seminar

MMA will hold a virtual auction seminar for qualified bidders prior to the lease sale. The auction seminar will begin at 11:00 a.m. on November 12, 2026.

- The seminar will not be open to the public.
- During the session, MMA will describe the auction process, explain

rules and procedures, and provide an opportunity for qualified bidders to ask questions.

Auction Details

The auction will be conducted pursuant to OCSLA and its implementing regulations at 30 CFR part 581.

- The auction will be conducted as an in-person, oral ascending clock auction, with each lease area auctioned sequentially.

• MMA will allow each qualified bidder to bid for and potentially acquire both lease areas. If an entity wishes to win both lease areas, it must submit two bid deposits. A bidder that submits only one bid deposit and does not win the first lease area may continue bidding for the second lease area.

- MMA will verify receipt of bid deposits prior to participation in the auction.

• Up to five individuals may attend the auction on behalf of a bidding entity. Bidding entities must advise MMA via email at pacific.region@boem.gov no later than 4:00 p.m. on Thursday, November 12, 2026, that they intend to participate in the auction, and include the list of individuals expected to attend. MMA will promptly respond to the email with additional instructions for attending the auction. Bidding entities who do not notify MMA and obtain advance approval for individuals to attend will not be granted access to the venue.

- The BFF must identify the individuals authorized to bid.
- An authorized representative of the qualified bidder must be present at the time of the lease sale to recertify the BFF.
- The authorized representative and persons authorized to bid must provide proof of identity matching the BFF.

IX. Bidding Rules

MMA will auction lease OCS-P 0569 first, followed by lease OCS-P 0568. The auction will proceed sequentially, one lease area at a time. The provisional winner of the first lease area will be permitted to bid for the second lease area, provided they submit the appropriate initial bonus bid deposit(s) in accordance with the instructions in the section entitled, "Bonus Bid Deposit."

For each lease area, the auction will be conducted in a series of rounds with incrementally higher prices, which will be set by MMA. In each round, all bidders will have the opportunity to signal participation within the specified time period. If a bidder fails to signal its participation at a given price, that will

indicate that the bidder has withdrawn from the bidding for that lease area. MMA will verify participation or withdrawal with each bidder at the close of the round and, once confirmed, either participation or withdrawal will be final. The auction will continue until only one bidder signals participation at a given price. That bidder becomes the provisional winner of the lease area.

When a bidder withdraws from bidding in a lease area by failing to signal participation at the next highest price, they will be asked to submit an exit bid, which is the highest price they are willing to pay for the lease area. The exit bid must be no lower than the round's price at which the bidder last signaled participation and must be below the price of the next round. If a bidder fails to submit an exit bid, the last price at which they signaled participation will be used as their exit bid. Exit bids are used if no bidders signal participation in a given round, a tie occurs, or the provisional winner does not meet the lease execution requirements or otherwise fails to comply with applicable regulations. In these cases, MMA reserves the right to offer the lease area to the bidder submitting the next highest bid offer as determined by MMA.

MMA will set a time limit for signaling participation within each round. The auction facilitator may close the round early if all active bidders have indicated their decision for the round. A warning will be issued before early closure. This time limit is set to expedite the sale procedure, but extensions may be granted upon request. A recess may be declared at any time the situation warrants, at the sole discretion of the Pacific Regional Director, or his or her designee.

The provisional winner of each lease area will pay the final bid deposit in accordance with the instructions in the section below entitled, "Bonus Bid Deposit." If the provisional winner does not submit the final bid deposit as outlined in the section entitled, "Bonus Bid Deposit," MMA, in its discretion, may retain the initial bid deposit and offer the area to the next highest bidder. Similarly, if the provisional winner does not follow through with the remainder of the bid as outlined in the section below entitled, "Lease Award," MMA, in its discretion, may retain the bid deposit and offer the area to the next highest bidder. A provisional winner will be disqualified if it is subsequently found to have violated auction rules, OCSLA, applicable regulations, or otherwise engaged in conduct detrimental to the integrity of the competitive auction.

Authorized Signatures

All signatories executing documents on behalf of the bidder(s) must execute the same in conformance with MMA qualification records. MMA considers any actions taken by an authorized bidder during the oral ascending clock auction process as a legally binding obligation on the part of the bidder(s) to comply with all applicable regulations, including fulfilling the bonus bid requirement for all high bids.

Bonus Bid Deposit

A bonus bid deposit of 20 percent of the total bid amount is required. Each bid deposit will be payable in two parts:

1. Each qualified bidder must submit an initial bonus bid deposit to the Office of Natural Resources Revenue (ONRR) equal to 20 percent of the minimum bid owed for each lease area it wishes to win. For example, if a bidder is interested in winning only one lease area, they would pay a bid deposit of \$600,000 (20% * \$3,000,000). If a bidder seeks the ability to win both lease areas, it must submit two bid deposits each in the amount of \$600,000. The initial bonus bid deposit(s) must be received by November 5, 2026, and will be electronically deposited into an interest-bearing account in the U.S. Treasury.

2. After the oral auction has ended, the provisional winning bidder for each lease area must pay a final bonus bid deposit by 2:00 p.m. on the first business day after the auction. The total bid deposit is 20 percent of the winning high bid. The amount owed in the final bonus bid deposit is 20 percent of the winning high bid less the initial bonus bid deposit already paid. If a bidder is the provisional winning bidder for both lease areas, it must submit two final bonus bid deposits.

MMA requires bidders to use EFT procedures for bonus bid deposit payments for this lease sale, following the detailed instructions contained on the ONRR Payment Information web page at <https://www.onrr.gov/paying>. Receipt of a bonus bid deposit does not constitute, and will not be construed as, acceptance of any bid on behalf of the United States. Non-winning bidders will have their initial bonus bid deposit(s) refunded.

Withdrawal of Blocks

The United States reserves the right to withdraw any block from this lease sale before issuance of a written acceptance of a bid for the block.

Acceptance, Rejection, or Return of Bids

The United States reserves the right to reject any and all bids, regardless of the amount offered. Furthermore, no bid

will be accepted, and no lease for any block will be awarded to any bidder, unless:

1. The bidder has complied with all applicable statutes, regulations and requirements of the FLN, including those set forth in the documents contained in this FLN package; and
2. The bid is the highest valid bid and meets or exceeds MMA's minimum bid in this FLN.

Any bid submitted that does not conform to the requirements of the FLN, OCSLA, or other applicable statute or regulation will be rejected and returned to the bidder. The United States Department of Justice and the Federal Trade Commission will review the results of this lease sale for any antitrust issues prior to the acceptance of bids and issuance of leases.

Lease Award

MMA will use Form BOEM-2004 (April 2026) to convey leases resulting from this sale. This lease form can be viewed on MMA's website at <https://www.boem.gov/about-boem/procurement-business-opportunities/boem-ocs-operation-forms>. The lease form will be amended to include specific terms, conditions, and stipulations applicable to the individual lease. Each bidder that is awarded a lease is required to complete the following within 10 business days of receipt of the lease from MMA:

1. Execute all copies of the lease (Form BOEM-2004 [April 2026], as amended); and
2. Pay by EFT the balance of the bonus bid amount for each lease issued in accordance with the requirements of the FLN and 30 CFR 1218.155 and 581.26.

ONRR requests that bidders use only one transaction for payment of the balance of the bonus bid amount. Once ONRR receives such payment, the bidder who has been awarded the lease may not request a refund of the balance of the bonus bid payment.

Unlawful Combination or Intimidation

MMA warns bidders against violation of 18 U.S.C. 1860, which prohibits unlawful combination or intimidation of bidders.

X. Delay of Sale

The MMA Pacific Regional Director has the discretion to change any date, time, and/or location specified in this FLN if the Regional Director deems that an emergent event could interfere with a fair and orderly lease sale. Such events could include, but are not limited to, natural disasters (e.g., earthquakes, fires or floods), wars, riots, acts of terrorism,

fires, strikes, civil disorder, or other events of a similar nature. In case of such events, bidders should call (805) 384-6305 or access the MMA website at <https://www.boem.gov/marine-minerals/american-samoa-activities>, for information regarding any changes.

Michael D. Olsen

Acting Director, Marine Minerals Administration.

[FR Doc. 2026-21462 Filed 10-19-26; 8:45 am]

BILLING CODE 4340-98-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-643 and 731-TA-1493 (Review)]

Small Vertical Shaft Engines From China; Determinations

On the basis of the record¹ developed in the subject five-year reviews, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that revocation of the countervailing and antidumping duty orders on small vertical shaft engines from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.²

Background

The Commission instituted these reviews on April 1, 2026 (91 FR 16231) and determined on July 6, 2026, that it would conduct expedited reviews (91 FR 50892, August 6, 2026).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on October 16, 2026. The views of the Commission are contained in USITC Publication 5801 (October 2026), entitled *Small Vertical Shaft Engines from China: Investigation Nos. 701-TA-643 and 731-TA-1493 (Review)*.

By order of the Commission.

Issued: October 16, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026-21459 Filed 10-19-26; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-810 and 731-TA-1811-1812 (Preliminary)]

Seamless Carbon and Alloy Steel Standard, Line, and Pressure Pipe From Georgia and India; Institution of Antidumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701-TA-810 and 731-TA-1811-1812 (Preliminary) pursuant to the Tariff Act of 1930 to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of seamless carbon and alloy steel standard, line, and pressure pipe from Georgia and India, provided for in subheadings 7304.19.10, 7304.19.50, 7304.31.60, 7304.39.00, 7304.51.50, 7304.59.60, and 7304.59.80 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of India. Unless the Department of Commerce ("Commerce") extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by November 30, 2026. The Commission's views must be transmitted to Commerce within five business days thereafter, or by December 7, 2026.

DATES: October 15, 2026.

FOR FURTHER INFORMATION CONTACT:

David McDonald (202-205-3331), 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

these investigations may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on October 15, 2026, by Vallourec Star, LP, Houston, Texas; Tenaris USA, Houston, Texas; and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO, CLC, Pittsburgh, Pennsylvania.

For further information concerning the conduct of these investigations 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 and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference—The Office of Investigations will hold a staff conference in connection with the preliminary phase of these investigations beginning at 9:30 a.m. on

¹ The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

² Commissioner Samuel T. Negatu not participating.

November 5, 2026. Requests to appear at the conference should be emailed to preliminaryconferences@usitc.gov (DO NOT FILE ON EDIS) on or before noon on November 3, 2026. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) | United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on November 10, 2026, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than 4:00 p.m. on November 4, 2026. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also 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 investigations must be served on all other parties to the investigations (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.

Certification—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In

making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations 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 these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: October 16, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–21458 Filed 10–19–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–781 and 731–TA–1768 (Final)]

Van-Type Trailers and Subassemblies From China; Determinations

On the basis of the record¹ developed in the subject investigations, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that an industry in the United States is materially injured by reason of imports of van-type trailers and subassemblies from China, provided for in subheadings 8716.39.00 and 8716.90.50 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce ("Commerce") to be sold in the United States at less than fair value ("LTFV"), and imports of the subject merchandise from China that have been found to be subsidized by the government of China.^{2 3}

¹ The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

² 91 FR 55837 (August 31, 2026) and 91 FR 55840 (August 31, 2026).

³ Commissioner Bartholomew Thanhauser and Commissioner Samuel Negatu not participating.

Background

The Commission instituted these investigations effective November 20, 2025, following receipt of petitions filed with the Commission and Commerce by the American Trailer Manufacturers Coalition, whose members are Great Dane LLC, Chicago, Illinois, Stoughton Trailers LLC, Stoughton, Wisconsin, and Wabash National Corporation, Lafayette, Indiana.⁴ The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of van-type trailers and subassemblies from China were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 17, 2026 (91 FR 36613). The Commission subsequently published a notice of revision to the schedule of these investigations in the **Federal Register** on August 18, 2026 (91 FR 53422). The Commission conducted its hearing on August 27, 2026. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on October 15, 2026. The views of the Commission are contained in USITC Publication 5797 (October 2026), entitled *Van-Type Trailers and Subassemblies from China: Investigation Nos. 701–TA–781 and 731–TA–1768 (Final)*.

By order of the Commission.

⁴ The petitions alleged that an industry in the United States is materially injured and threatened with material injury by reason of subsidized and LTFV imports of van-type trailers and subassemblies from Canada, China, and Mexico. Following withdrawal of the countervailing duty petition on van-type trailers and subassemblies from Canada the Commission on June 17, 2026, published notice in the **Federal Register** of termination of its countervailing duty investigation on imports from Canada (91 FR 36615). The remaining investigations regarding imports of van-type trailers and subassemblies from Mexico and Canada are ongoing.

Issued: October 15, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–21382 Filed 10–19–26; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jefferson Burroughs, M.D.; Decision and Order

On March 31, 2026, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Jefferson Burroughs, M.D., of Cincinnati, Ohio (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. BB2526741, alleging that Registrant is "currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of Ohio, the state in which [he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).¹

The OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 2 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing, and the Agency finds him to be in default. RFAA, at 2.² "A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may

enter a default final order pursuant to [21 CFR] 1316.67." *Id.* 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 3; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e).

According to the OSC, on July 1, 2025, Registrant's Ohio medical license expired by its own terms. RFAAX 2, at 1. According to Ohio online records, of which the Agency takes official notice, Registrant's Ohio medical license is expired.³ eLicense Ohio Professional Licensure License Lookup, https://elicense.ohio.oh_verifylicense (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice medicine in Ohio, the state in which he is registered with DEA.⁴

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 his 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. 243, 270 (2006) ("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 physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices' to dispense controlled substances. 802(21).")⁵ The Agency has applied these principles consistently. *See, e.g., Craig Cohen, DPM*, 91 FR 57922 (2026); *Thomas Earley, D.D.S.*, 91 FR 55624 (2026); *Henry-Norbert O. Ndekwe, M.D.*, 90 FR 15990 (2025).

According to Ohio statute, "[n]o person shall knowingly obtain, possess, or use a controlled substance or a controlled substance analog," except pursuant to a "prescription issued by a licensed health professional authorized to prescribe drugs if the prescription was issued for a legitimate medical purpose." Ohio Rev. Code §§ 2925.11(A), (B)(1)(d) (2025). Further, a "[l]icensed health professional authorized to prescribe drugs" or 'prescriber' means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice." *Id.* § 4729.01(I) (2026).⁶ The Ohio statute further defines an authorized prescriber as "[a] physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery." *Id.* § 4729.01(I)(5) (2026). Additionally, Ohio law permits "[a] licensed health professional authorized to prescribe drugs, if acting in the course of

⁵ 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 . . . 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., Elias Garcia Garcia, P.A.*, 90 FR 31242 (2025); *Jason Weakley, R.N., A.P.R.N.*, 90 FR 10085 (2025); *Khursheed Haider, M.D.*, 90 FR 21950 (2025).

⁶ Section 4729.01 of the Ohio Revised Code was updated on October 9, 2026, but does not change any of the material parts or alter the Agency's decision in this matter.

¹ According to Agency records, Registrant's registration expired on July 31, 2026. The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.*, 84 FR 68474, 68476–79 (2019).

² Based on the Government's submissions in its RFAA dated July 23, 2026, the Agency finds that service of the OSC on Registrant was adequate. The included declaration from a DEA Diversion Investigator (DI) indicates that on or about April 1, 2026, the DI, accompanied by a Financial Investigator, traveled to Registrant's residential address, where Registrant's wife accepted a copy of the OSC and signed the Form DEA–12 confirming receipt. RFAAX 3, at 2; *see also id.*, Attachment B. On or about April 2, 2026, the DI received a call from Registrant during which Registrant confirmed receipt of the OSC. *Id.* at 2.

³ 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).

⁴ 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 practice medicine in Ohio. Accordingly, Registrant may dispute the Agency's findings 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.

professional practice, in accordance with the laws regulating the professional's practice" to prescribe or administer schedule II, III, IV, and V controlled substances to patients. *Id.* § 3719.06(A)(1)(a)–(b) (2025).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice medicine in Ohio. As discussed above, an individual must be a licensed health professional authorized to prescribe drugs in order to handle controlled substances in Ohio. Thus, because Registrant is not a licensed health professional authorized to prescribe drugs in Ohio, and, therefore, is not authorized to handle controlled substances in Ohio, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BB2526741 issued to Jefferson Burroughs, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Jefferson Burroughs, M.D., to renew or modify this registration, as well as any other pending application of Jefferson Burroughs, M.D., for additional registration in Ohio. This Order is effective November 19, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 14, 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. 2026–21413 Filed 10–19–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Peter Michael Wills, D.D.S.; Decision and Order

On March 31, 2026, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Peter Michael Wills, D.D.S., of Middletown, Ohio (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. AW4788343, alleging that Registrant is "currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of Ohio, the state in which [he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).¹

The OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 2 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing, and the Agency finds him to be in default. RFAA, at 2.² "A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67." *Id.* 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 3; *see also* 21 CFR 1316.67.

¹ According to Agency records, Registrant's registration expired on May 31, 2026. The fact that a registrant allows his registration to expire during the pendency of an OSC does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.*, 84 FR 68474, 68476–79 (2019).

² Based on the Government's submissions in its RFAA dated May 21, 2026, the Agency finds that service of the OSC on Registrant was adequate. The included declaration from a DEA Diversion Investigator (DI) indicates that on or about April 2, 2026, the DI, accompanied by another DI, traveled to Registrant's residential address and personally served the OSC on Registrant. RFAAX 3, at 2; *see also id.*, Attachment B (Form DEA–12 signed by Registrant acknowledging receipt of the OSC).

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. According to the OSC, Registrant's Ohio dental license expired by its own terms on December 31, 2025. RFAAX 2, at 1. According to Ohio online records, of which the Agency takes official notice, Registrant's Ohio dental license is expired.³ eLicense Ohio Professional Licensure License Lookup, <https://elicense.ohio.gov/verifylicense> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice dentistry in Ohio, the state in which he is registered with DEA.⁴

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 his 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. 243, 270 (2006) ("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 physicians 'licensed, registered, or otherwise permitted, by the United States or the jurisdiction in

³ 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).

⁴ 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 practice dentistry in Ohio. 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.

which he practices' to dispense controlled substances. 802(21).")⁵ The Agency has applied these principles consistently. *See, e.g., Craig Cohen, DPM*, 91 FR 57922 (2026); *Thomas Earley, D.D.S.*, 91 FR 55624 (2026); *Henry-Norbert O. Ndekwe, M.D.*, 90 FR 15990 (2025).

According to Ohio statute, "[n]o person shall knowingly obtain, possess, or use a controlled substance or a controlled substance analog," except pursuant to a "prescription issued by a licensed health professional authorized to prescribe drugs if the prescription was issued for a legitimate medical purpose." Ohio Rev. Code § 2925.11(A), (B)(1)(d) (2025). Further, a "[l]icensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice." *Id.* § 4729.01(I). The Ohio statute further defines an authorized prescriber as "[a] dentist licensed under Chapter 4715. of the Revised Code." *Id.* § 4729.01(I)(1). Additionally, Ohio law permits "[a] licensed health professional authorized to prescribe drugs, if acting in the course of professional practice, in accordance with the laws regulating the professional's practice" to prescribe or administer schedule II, III, IV, and V controlled substances to patients. *Id.* § 3719.06(A)(1)(a)–(b).

Here, the undisputed evidence in the record is that Registrant lacks authority to practice dentistry in Ohio. As discussed above, an individual must be a licensed health professional authorized to prescribe drugs in order to handle controlled substances in Ohio. Thus, because Registrant is not a licensed health professional authorized to prescribe drugs in Ohio, and, therefore, is not authorized to handle

controlled substances in Ohio, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. AW4788343 issued to Peter Michael Wills, D.D.S. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Peter Michael Wills, D.D.S., to renew or modify this registration, as well as any other pending application of Peter Michael Wills, D.D.S., for additional registration in Ohio. This Order is effective November 19, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 14, 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. 2026–21415 Filed 10–19–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jan Pijanowski, M.D.; Decision and Order

On June 9, 2026, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Jan Pijanowski, M.D., of Parma Heights, Ohio (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. FP3656153, alleging that Registrant is "currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of Ohio, the state in which

[he is] registered with DEA." *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of his right to file a written request for hearing, and that if he failed to file such a request, he would be deemed to have waived his right to a hearing and be in default. *Id.* at 2 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing, and the Agency finds him to be in default. RFAA, at 2.¹ "A default, unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC]." 21 CFR 1301.43(e).

Further, "[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67." *Id.* 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). According to the OSC, Registrant's Ohio medical license expired on July 14, 2025. RFAAX 1, at 1. According to Ohio online records, of which the Agency takes official notice, Registrant's Ohio medical license status remains expired.² eLicense Ohio Professional Licensure License Lookup, https://elicense.ohio.gov/oh_verifylicense (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice medicine in Ohio, the state in which he is registered with DEA.³

¹ Based on the Government's submissions in its RFAA dated July 30, 2026, the Agency finds that service of the OSC on Registrant was adequate. The included declaration from a DEA Diversion Investigator (DI) indicates that on June 12, 2026, Registrant was personally served with a copy of the OSC. RFAAX 3, at 1–2 (Form-DEA 12 signed by Registrant, acknowledging receipt of the OSC); RFAAX 3, Appendix B, at 1.

² 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).

³ 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

⁵ 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 . . . 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., Elias Garcia Garcia, P.A.*, 90 FR 31242 (2025); *Jason Weakley, R.N., A.P.R.N.*, 90 FR 10085 (2025); *Khurshed Haider, M.D.*, 90 FR 21950 (2025).

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 his 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. 243, 270 (2006) (“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 physicians ‘licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices’ to dispense controlled substances. 802(21).”) ⁴ The Agency has applied these principles consistently. *See, e.g., Lawrence Rudolph, D.M.D.*, 89 FR 79310 (2024); *Henry-Norbert O. Ndekwe, M.D.*, 90 FR 15990 (2025); *Benson Sergiles, P.A.*, 90 FR 32016 (2025).

According to Ohio statute, “[n]o person shall knowingly obtain, possess,

licensed to practice medicine in Ohio. 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.

⁴ 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 . . . 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., Elias Garcia Garcia, P.A.*, 90 FR 31242 (2025); *Jason Weakley, R.N., A.P.R.N.*, 90 FR 10085 (2025); *Khursheed Haider, M.D.*, 90 FR 21950 (2025).

or use a controlled substance or a controlled substance analog,” except pursuant to a “prescription issued by a licensed health professional authorized to prescribe drugs if the prescription was issued for a legitimate medical purpose.” Ohio Rev. Code § 2925.11(A), (B)(1)(d) (2025). Further, a “[l]icensed health professional authorized to prescribe drugs or ‘prescriber’ means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual’s professional practice.” *Id.* § 4729.01(I). The Ohio statute further defines an authorized prescriber as “[a] physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.” *Id.* 4729.01(I)(5). Additionally, Ohio law permits “[a] licensed health professional authorized to prescribe drugs, if acting in the course of professional practice, in accordance with the laws regulating the professional’s practice” to prescribe or administer schedule II, III, IV, and V controlled substances to patients. *Id.* § 3719.06(A)(1)(a)–(b).

Here, the undisputed evidence in the record is that Registrant lacks a license to practice medicine in Ohio. As already discussed, a physician is authorized by law to prescribe or administer drugs in Ohio only when authorized to practice medicine under Ohio law. Thus, because Registrant lacks authority to practice medicine in Ohio and, therefore, is not authorized to handle controlled substances in Ohio, Registrant is not eligible to maintain a DEA registration in Ohio. Accordingly, the Agency will order that Registrant’s DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FP3656153 issued to Jan Pijanowski, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Jan Pijanowski, M.D., to renew or modify this registration, as well as any other pending application of Jan Pijanowski, M.D., for additional registration in Ohio. This Order is effective November 19, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 14, 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. 2026–21414 Filed 10–19–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Younma Abdulhadi, M.D.; Decision and Order

On March 17, 2026, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Younma Abdulhadi, M.D., of El Centro, California (Registrant). Request for Final Agency Action (RFAA), Exhibit (RFAAX) 2, at 1, 3. The OSC proposed the revocation of Registrant’s Certificate of Registration No. FA2682967, alleging that Registrant is “currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of California, the state in which [she is] registered with DEA.” *Id.* at 2. (citing 21 U.S.C. 824(a)(3)).¹

The OSC notified Registrant of her right to file a written request for hearing, and that if she failed to file such a request, she would be deemed to have waived her right to a hearing and be in default. *Id.* at 2 (citing 21 CFR 1301.43). Here, Registrant did not request a hearing, and the Agency finds her to be in default. RFAA, at 3.² “A default,

¹ According to Agency records, Registrant’s registration expired on June 30, 2026. The fact that a registrant allows her registration to expire during the pendency of an OSC does not impact the Agency’s jurisdiction or prerogative under the Controlled Substances Act (CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.*, 84 FR 68474, 68476–68479 (2019).

² Based on the Government’s submissions in its RFAA dated June 23, 2026, the Agency finds that service of the OSC on Registrant was adequate. The included declaration from a DEA Diversion Investigator (DI) indicates that on or about March 30, 2026, the DI traveled with a Special Agent (SA) to Registrant’s last known residential address to attempt in-person service but was unsuccessful. RFAAX 3, at 2. On the same date, the DI emailed Registrant a copy of the OSC at her registered email address. *Id.* at 3; *see also id.*, Attachment C. On or about March 31, 2026, the DI traveled with another SA and a Task Force Officer (TFO) to Registrant’s

Continued

unless excused, shall be deemed to constitute a waiver of the registrant's/applicant's right to a hearing and an admission of the factual allegations of the [OSC].” 21 CFR 1301.43(e).

Further, “[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] 1316.67.” *Id.* at 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default pursuant to 21 CFR 1301.43(c), (f), and 1301.46. RFAA, at 4; *see* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are deemed admitted. 21 CFR 1301.43(e). According to the OSC, effective December 4, 2024, the Medical Board of California revoked Registrant's California medical license. RFAAX 2, at 2. According to California online records, of which the Agency takes official notice,³ Registrant's California medical license has a primary status of “License Revoked.” California DCA License Search, <https://search.dca.ca.gov> (last visited date of signature of this Order). Accordingly, the Agency finds that Registrant is not licensed to practice medicine in California, the state in which she is registered with DEA.⁴

registered address to attempt in-person service but was again unsuccessful. *Id.* at 3. On the same date, the DI also mailed a copy of the OSC to Registrant's registered address. *Id.* On or about April 1, 2026, the DI mailed another copy of the OSC to a newly discovered address associated with Registrant. *Id.* Finally, on the same date, the DI emailed a copy of the OSC to two newly discovered email addresses associated with Registrant. *Id.*; *see also id.*, Attachments D–E. Here, the Agency finds that Registrant was successfully served the OSC by email and that the DI's efforts to serve Registrant by other means were “‘reasonably calculated, under all the circumstances, to apprise [Registrant] of the pendency of the action.’” *Jones v. Flowers*, 547 U.S. 220, 226 (2006) (quoting *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950)). Therefore, due process notice requirements have been satisfied. *See Mohammed S. Aljanaby, M.D.*, 82 FR 34552, 34552 (2017) (finding that service by email satisfies due process where the email is not returned as undeliverable and other methods have been unsuccessful); *Emilio Luna, M.D.*, 77 FR 4829, 4830 (2012) (same).

³ 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).

⁴ 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

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 his 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. 243, 270 (2006) (“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 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., James L. Hooper, M.D.*, 76 FR 71371, 71372 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27616, 27617 (1978).⁵

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 practice medicine in California. 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.

⁵ This rule derives from the text of two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a physician . . . 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., James L. Hooper, M.D.*, 76 FR at 71371–72; *Sheran Arden Yeates, M.D.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51104, 51105

According to California statute, “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, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery.” Cal. Health & Safety Code § 11010 (West 2026). Further, a “practitioner” means a person “‘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 [the] state.’” *Id.* § 11026(c).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As discussed above, an individual must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant currently lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, the Agency will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FA2682967 issued to Youmna Abdulhadi, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny any pending applications of Youmna Abdulhadi, M.D., to renew or modify this registration, as well as any other pending application of Youmna Abdulhadi, M.D., for additional registration in California. This Order is effective November 19, 2026.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 14, 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

(1993); *Bobby Watts, M.D.*, 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton, M.D.*, 43 FR at 27617.

the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2026–21410 Filed 10–19–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB 1140–0056]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Revising a Previously Approved Collection; Special Agent Medical Preplacement—ATF Form 2300.10

AGENCY: Bureau of Alcohol, Tobacco, Firearms, and Explosives; Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), will be submitting the following information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: ATF encourages comments on this information collection. You may submit written comments until midnight on December 21, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection, especially on the estimated public burden or associated response time, to Dawn Cheeks, Workforce Wellness and Services Division (WWSD), by email to preemploymentmedical@atf.gov, or by mail to WWSD, Room 2.S–265; Wellness, Resiliency, and Advocacy Programs (WRAP); 99 New York Avenue NE, Washington, DC 20226. Identify comments by the OMB control number 1140–0056. You may view the proposed information collection instrument online at <https://www.atf.gov/rules-and-regulations/federal-register-actions/forms-and-information-collection>.

FOR FURTHER INFORMATION CONTACT: If you have questions or need a copy of the proposed information collection instrument with instructions or additional information, contact Dawn Cheeks, WWSD, either by mail at WWSD, Room 2.S–265; Wellness, Resiliency, and Advocacy Programs (WRAP); 99 New York Avenue NE, Washington, DC 20226, by email at

preemploymentmedical@atf.gov, or by telephone at 202.412.1770. If you require additional information on DOJ's ICR process for this renewal request, contact Darwin Arceo, Department Clearance Officer; United States Department of Justice; Justice Management Division, Policy and Planning Staff; Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

SUPPLEMENTARY INFORMATION: We encourage written comments and suggestions from the public and affected agencies concerning the proposed information collection. Your comments should address one or more of the following four points:

- Evaluate whether the proposed information collection is necessary to properly perform ATF's functions, including whether the information will have practical utility;
- Evaluate the agency's estimate of the proposed information collection's burden for accuracy, including validity of the methodology and assumptions used;
- Evaluate whether the quality, utility, and clarity of the information being collected can be enhanced, and if so, how; and
- Minimize the information collection's burden on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting people to submit electronic responses.

Overview of This Information Collection

Abstract: Medical standards are part of the general requirement for specific positions in the federal government. Medical requirements are created for positions that involve arduous/hazardous duties or require a high standard of human reliability. Failing to meet an established medical standard or physical requirement means that the individual is not qualified for the position. 5 CFR 339.301 authorizes agencies to require a routine pre-appointment examination as part of qualifying for a position with specific medical standards. The Office of Personnel Management (OPM) identified the positions of criminal investigator (special agent), GL/GS–1811, and explosives enforcement officer, GS–1801, as having specific medical requirements. The qualification

standard for Criminal Investigation series (special agent) and General Inspection, Investigation, Enforcement, and Compliance series (explosives enforcement officer) are published online in OPM's *General Schedule Qualification Standards*. These medical requirements are part of the basic prerequisites for both positions. ATF uses ATF Form 2300.10, Special Agent Medical Preplacement, to collect specific identifiable data, such as the name, address, telephone, social security number, and medical data, necessary to identify the applicant and to assess whether they meet the positions' qualification standards. The applicant completes the first part of the form, and the doctor/health care provider completes the second part. Applicants from outside ATF use the form to apply for these positions, and existing special agents and explosives enforcement officers who are applying for similar positions at ATF also use the form. The information on the form is used to determine medical suitability for these positions.

Type of information collection: revising a previously approved collection.

Title of the form/collection: Special Agent Medical Preplacement.

Agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number: ATF Form 2300.1. *Component:* Bureau of Alcohol, Tobacco, Firearms, and Explosives.

Affected public who will be asked or required to respond, as well as the obligation to respond: Affected public: individuals. *Obligation to respond:* required to obtain a benefit.

Estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: ATF estimates 1,000 respondents associated with this collection per year, and it will take each respondent an average of approximately 45 minutes (0.75 hours) per response to complete their responses.

Estimate of the total annual burden (in hours) associated with the collection: The estimated annual public burden associated with this collection is 750 hours, which is equal to 1,000 (total respondents) * 1 (# of responses per respondent) * 0.75 hours.

Estimate of the total annual other cost burden associated with the collection, if applicable: 0; there are no costs.

ESTIMATED TOTAL HOURLY BURDEN

Activity	Number of respondents	Frequency	Total annual responses	Time per response (hours)	Total annual burden (hours)
Completing application	1,000	1	1,000	0.75	750

Revisions to This Information Collection

As part of this ICR renewal, ATF is making no revisions to this information collection, OMB 1140–0056. However, ATF anticipates a program change affecting this information collection, in that ATF anticipates an increase in hiring for affected positions over the next three years. As a result, ATF adjusted the hourly burden due to a significant projected increase in the annual number of respondents since the last renewal, from 380 to 1,000, an increase of 620. This resulted in a corresponding increase in the total number of burden hours associated with this IC from 285 during the last renewal, up by 465 hours to 750 hours for this renewal.

Dated: October 16, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–21446 Filed 10–19–26; 8:45 am]

BILLING CODE 4410–FY–P

LEGAL SERVICES CORPORATION**Sunshine Act Meetings**

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 91 FR 64693.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: The Institutional Advancement Committee of the Legal Services Corporation Board of Directors will meet on October 21, 2026, 2:00 p.m. Eastern Time.

CHANGES IN THE MEETING: The matters to be discussed during the open session meeting of the Institutional Advancement Committee have changed. Matters to be discussed now also include endowment opportunities for planned giving; and considering and acting on a motion to ratify acceptance of an endowment fund.

CONTACT PERSON FOR MORE INFORMATION: Kimberly Little, Board and Executive Coordinator, at (202) 295–1500. Questions may also be sent by electronic mail to the Office of the Corporate Secretary at updates@lsc.gov.

(Authority: 5 U.S.C. 552b.)

Dated: October 16, 2026.

Stefanie Davis,

Deputy General Counsel, Legal Services Corporation.

[FR Doc. 2026–21449 Filed 10–16–26; 4:15 pm]

BILLING CODE 7050–01–P

MILLENNIUM CHALLENGE CORPORATION

[MCC FR 26–11]

Notice of Open Meeting

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Federal Advisory Committee Act, the Millennium Challenge Corporation (MCC) Advisory Council was established as a discretionary advisory committee on July 14, 2016. Its charter was most recently reestablished on September 30, 2026. The MCC Advisory Council serves MCC solely in an advisory capacity and provides insight regarding innovations in infrastructure, technology, and sustainability; perceived risks and opportunities in MCC partner countries; new financing mechanisms for developing country contexts; and shared value approaches. The MCC Advisory Council provides a platform for systematic engagement with the private sector and other external stakeholders and contributes to MCC's mission—to reduce poverty through sustainable economic growth.

DATES: Tuesday, October 27, 2026, from 9:30 a.m.–12:00 p.m. EDT.

ADDRESSES: The meeting will be hybrid, via in-person and conference call.

FOR FURTHER INFORMATION CONTACT: Email MCCAdvisoryCouncil@mcc.gov, contact Sheena Cooper at (202) 733–7148, or visit <https://www.mcc.gov/about/org-unit/advisory-council> for more information.

SUPPLEMENTARY INFORMATION:

Agenda. During the Fall 2026 meeting of the MCC Advisory Council members will receive updates on the MCC's private sector strategy presented at January's council meeting and MCC's next steps in operationalizing the strategy. Additionally, members will be

provided an update on all MCC portfolio countries.

Public Participation. The meeting will be open to the public. Members of the public may file written statement(s) before or after the meeting. If you plan to attend, please submit your name and affiliation no later than Friday, October 23, 2026, to MCCAdvisoryCouncil@mcc.gov to receive instructions on how to attend.

(Authority: Federal Advisory Committee Act, 5 U.S.C. App.)

Dated: October 15, 2026.

Brian Finkelstein,

Acting Vice President, General Counsel, and Corporate Secretary.

[FR Doc. 2026–21392 Filed 10–19–26; 8:45 am]

BILLING CODE 9211–03–P

NATIONAL CREDIT UNION ADMINISTRATION**Renewal of Agency Information Collections for Comments Request: Proposed Collections**

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comments.

SUMMARY: The National Credit Union Administration (NCUA) 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.

DATES: Written comments should be received on or before December 21, 2026 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dacia Rogers, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314, Suite 6055; Fax No. (703) 519–8161; or email at PRAComments@NCUA.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by contacting Dacia Rogers at (703) 518–6547.

SUPPLEMENTARY INFORMATION:
OMB Number: 3133–0040.

Title: Federal Credit Union Occupancy, Planning, and Disposal of Acquired and Abandoned Premises—12 CFR 701.36.

Type of Review: Extension of a previously approved collection.

Abstract: Section 107(4) of the Federal Credit Union Act authorizes a federal credit union (FCU) to purchase, hold, and dispose of property necessary or incidental to its operations. Section 701.36 of NCUA Rules and Regulations interprets and implements this provision of the FCU Act by establishing occupancy, planning, and disposal requirements for acquired and abandoned premises. It also prohibits certain transactions. In addition, this section includes provisions in which an FCU may seek a waiver from certain requirements of the rule. NCUA reviews written waiver requests and makes a determination on the request based on safety and soundness considerations.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 160.

OMB Number: 3133–0061.

Title: Central Liquidity Facility, 12 CFR part 725.

Type of Review: Extension of a previously approved collection.

Abstract: Part 725 contains the regulations implementing the National Credit Union Central Liquidity Facility Act, subchapter III of the Federal Credit Union Act. The NCUA Central Liquidity Facility is a mixed-ownership Government corporation within NCUA. It is managed by the NCUA Board and is owned by its member credit unions. The purpose of the Facility is to improve the general financial stability of credit unions by meeting their liquidity needs and thereby encourage savings, support consumer and mortgage lending and provide basic financial resources to all segments of the economy. The Central Liquidity Facility achieves this purpose through operation of a Central Liquidity Fund (CLF). The collection of information under this part is necessary for the CLF to determine credit worthiness, as required by 12 U.S.C. 1795e(2).

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 119.

OMB Number: 3133–0141.

Title: Organization and Operations of Federal Credit Unions—Loan Participation, 12 CFR 701.22.

Type of Review: Extension of a previously approved collection.

Abstract: NCUA Rules and Regulations, sections 701.22 and

741.225, outline the requirements for a loan participation program. FICUs are required to execute a written loan participation agreement with the lead lender. Additionally, the rule requires all FICUs to maintain a loan participation policy that establishes underwriting standards and maximum concentration limits. Credit unions may apply for waivers on certain key provisions of the rule.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 2,916.

OMB Number: 3133–0199.

Title: Capital Planning and Stress Testing, 12 CFR 702–E.

Type of Review: Extension of a previously approved collection.

Abstract: To protect the National Credit Union Share Insurance Fund (NCUSIF) and the credit union system, the largest Federally Insured Credit Unions (FICUs) must have systems and processes to monitor and maintain their capital adequacy. The rule requires covered credit unions to develop and maintain a capital plan and submit this plan to NCUA by March 31 of each year. The rule applies to all FICUs that report \$10 billion or more in assets on their March 31 Call Report.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 11,710.

OMB Number: 3133–0210.

Title: Supervisory Stress Test Annual Data Collection, 12 CFR part 702, subpart C.

Type of Review: Extension of a previously approved collection.

Abstract: The NCUA Board (Board) has determined, to protect the National Credit Union Share Insurance Fund (NCUSIF) and the credit union system, that the largest Federally Insured Credit Unions (FICUs) should have systems and processes in place to monitor and maintain their capital adequacy. Subpart C of part 702 of NCUA's regulations codifies capital planning and stress testing requirements for federally insured credit unions with \$10 billion or more in assets (covered credit unions). Covered credit unions are further delineated by asset tiers. Tier I are credit union with \$10 billion or more in total assets, but less than \$15 billion in total assets; tier II are credit union with \$15 billion or more in total assets, but less than \$20 billion in total assets; and tier III are credit union with \$20 billion or more in total assets. Tier II and III credit unions are required to conduct supervisory stress tests and section 702.306 (b) codifies that NCUA

reserves the right to conduct stress tests of covered credit unions at any time and where both NCUA and a covered credit union have conducted the tests, the results of NCUA's tests will determine whether the covered credit union has met the requirements of this subpart. To facilitate NCUA's ability to conduct supervisory stress test on covered credit unions, section 702.306(d) requires that covered credit unions must provide NCUA with any relevant qualitative or quantitative information requested by NCUA pertinent to capital plans or stress test under this part.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 224.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By the National Credit Union Administration Board.

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2026–21444 Filed 10–19–26; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to establish this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public to comment on this action. After obtaining and considering public comments, 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 21, 2026 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT:

Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, Randolph Building, 401 Dulany Street, Alexandria, Virginia 22314; telephone (703) 292-7556; or send email to splimpto@nsf.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: Evidence and Evaluation Measurement Generic Clearance for the Directorate for Technology, Innovation and Partnerships (TIP)

OMB Control No.: 3145-NEW.

Expiration Date of Approval: Not applicable.

Type of Request: Request for approval of a new information collection.

Proposed Project: The U.S. National Science Foundation (NSF), Directorate for Technology, Innovation and Partnerships (TIP), is establishing the TIP Evidence and Evaluation Measurement Framework as a generic clearance to support data collection for evidence building, evaluation, and organizational learning. The Framework will encompass information collections across three broad areas of TIP investment: *technology translation*, *workforce development*, and *regional innovation ecosystems*. The generic clearance will provide a common structure for data collection across these three areas while allowing individual data collections to be tailored to their specific purpose, context, and respondent population.

Established by the CHIPS and Science Act of 2022, TIP was created to strengthen the Nation's innovation ecosystem. To fulfill this mission, TIP advances three broad strategic priorities: (1) accelerating critical and emerging technologies, (2) building a competition-ready workforce, and (3) expanding the geography of American innovation, all through partnerships that span academia, industry, government, nonprofit organizations, and other sectors. Accordingly, TIP's investments are designed around these strategic priorities to advance technology translation and commercialization,

workforce development, regional innovation, and partnerships.

Across the three areas covered by the Framework, the scope of data collected will be generally similar and will include descriptive and contextual information; customer, participant, and stakeholder experiences and satisfaction; and information on the activities, outputs, outcomes, and impacts of TIP investments. For example, within the technology translation area, data may include project and organizational characteristics, intellectual property development, technology validation and testing, commercialization activities, partnerships, follow-on investments, adoption barriers and risks, and other indicators of technology translation. Information collected within the workforce development and regional innovation ecosystem areas will similarly reflect the activities, outputs, outcomes, and impacts relevant to those areas.

The Framework will also support the development, testing, and evaluation of data collection techniques and methods, as appropriate to individual projects conducted under the generic clearance. These activities may include, but are not limited to, survey pretesting, pilot testing, focus groups, and testing alternative data collection approaches. Insights obtained through these activities may be used to assess and improve data collection instruments and methods, test alternatives, evaluate current approaches, and inform subsequent data collection and evaluation activities.

The data collected under the Framework is intended to address evidence needs across TIP's investment portfolio. Existing administrative data can provide information about awards and selected outputs but may not capture the activities, experiences, conditions, and outcomes necessary to understand TIP investments and their results. Data collected under the Framework will supplement existing administrative information and contribute to TIP's evidence-building, evaluation, and organizational activities.

Following standard OMB requirements, TIP will submit an individual request to OMB for each information collection undertaken under this generic clearance, and will obtain OMB approval prior to implementation. TIP will provide OMB with the proposed scope of the collection, how it aligns with TIP's three evidence areas covered by the Framework, the associated respondent burden, and a copy of the data collection instrument and related

materials. This approach will provide TIP flexibility to tailor data collection instruments and methods to program objectives and respondent characteristics, and to undertake development and testing activities described above. Together, these flexibilities will strengthen the quality and credibility of the evidence generated under the Framework.

Respondents: The respondents generally have the education and/or experience level commensurate to a university associate professor.

Estimated Number of Annual Respondents: 3,000.

Burden on the Public: Over the three years of the requested generic clearance, TIP estimates that approximately 3,000 principal investigators (PIs) will respond annually, with an average burden of one hour per respondent. This results in an estimated annual reporting burden of approximately 3,000 hours or 9,000 hours over the three-year clearance period. The estimated burden for individual information collections may vary depending on the methods used. For example, focus groups may require longer participation times, while surveys generally require less time. The total cumulative burden associated with all information collections conducted under the generic clearance will not exceed the approved burden estimate.

Dated: October 16, 2026.

Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.

[FR Doc. 2026-21466 Filed 10-19-26; 8:45 am]

BILLING CODE 7555-01-P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Grantee Reporting Requirements for the U.S. National Science Foundation Regional Innovation Engines (NSF Engines) Program

AGENCY: National Science Foundation (NSF).

ACTION: Notice with comment period.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing an opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by December 21, 2026, to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

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.

FOR FURTHER INFORMATION CONTACT:

Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, Randolph Building, 401 Dulany Street, Alexandria, Virginia 22314; telephone (703) 292-7556; or send email to splimpto@nsf.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: Grantee Reporting Requirements for the U.S. National Science Foundation Regional Innovation Engines (NSF Engines) Program.

OMB Control Number: 3145-0284.

Expiration Date of Approval: December 31, 2026.

Type of Request: Request for approval to renew an information collection.

Proposed Project: The U.S. National Science Foundation Regional Innovation Engines (Engines) program, led by NSF's Directorate for Technology, Innovation and Partnerships (TIP), is NSF's flagship investment in place-based innovation. Established pursuant to the CHIPS and Science Act of 2022, the program invests in regions across the United States to bring together the research, talent, partnerships, and resources needed to turn advances in science and technology into economic and societal benefits. Each NSF Engine serves a defined geographic Region of Service (RoS), the area intended to benefit from the NSF Engine's activities

and investments, and is organized around technologies and challenges important to that region and the Nation.

Specifically, the program seeks to:

- Advance key technology areas critical to U.S. competitiveness;
- Address pressing national and societal challenges;
- Cultivate partnerships across industry, academia, government, nonprofit organizations, civil society and communities of practice;
- Promote economic growth and job creation; and
- Develop the regional workforce and talent needed to sustain innovation.

Each NSF Engine carries out these objectives through three core functions: use-inspired research and development, translation of innovation results to society, and workforce development. Together, these activities are intended to strengthen a RoS's capacity to develop and commercialize new technologies, create and grow businesses, prepare workers for new opportunities, and attract additional investment. Over time, NSF Engines are expected to develop into sustainable regional innovation ecosystems that contribute to economic growth and U.S. competitiveness.

NSF Engines are substantial, long-term investments. Each NSF Engine may receive NSF funding for up to 10 years, based on its performance and progress toward established goals and milestones. As NSF Engines develop, their activities, partnerships, and sources of support are expected to grow and evolve. Regular reporting on a defined cadence helps NSF Engines teams track performance, identify and address issues, and adjust their strategies as needed. At the same time, it allows NSF to assess progress across the portfolio, identify risks and emerging challenges, and make informed program management and funding decisions.

Project Reporting Requirements: NSF is seeking renewed approval from the Office of Management and Budget (OMB) for the revised *Grantee Reporting Requirements for NSF Engines Program* information collection. The collection consists of four reporting components: (1) Quarterly Reports; (2) the Engine Report Template; (3) the Strategic and Implementation Plan; and (4) the Strategic Growth Plan. Each serves a distinct purpose; together, they provide NSF with information to monitor the implementation, performance, and development of each NSF Engine over the life of the award and the program holistically.

Quarterly Reports will be required in the first quarter (Q1) and third quarter (Q3) of the first year. These reports

provide timely information on NSF Engine operations, implementation, performance, and emerging issues. The two *Quarterly Reports* cover the first year and include the following required narrative sections:

1. Personnel, Governance and Operations;
2. Programmatic Activities; and
3. Partners and New Collaborations.

The *Engines Report Template (ERT)* will be submitted semiannually throughout the ten (10) years of the award in lieu of the NSF Research Performance Progress Report (RPPR). The ERT consists of two components: a tabular component for quantitative information, and a narrative component for qualitative information. The tabular component collects standardized and structured information across 10 areas:

1. Personnel;
2. Programmatic Activities;
3. Research, Development and Translation (RD&T) Outputs;
4. Workforce Development (WFD) Outputs;
5. Innovation Ecosystem Building Actions;
6. Innovation Ecosystem Building Infrastructure;
7. Partners;
8. Non-Partner Commitments and Resources;
9. Risk and Opportunity Register; and
10. Awardee Specified Metrics.

The narrative component provides context for the information reported in these areas, including implementation progress, challenges, and outcomes. Award recipients will also describe significant changes since the previous reporting period and, as applicable, explain deviations from previously established plans. Together, the quantitative and qualitative components allow NSF to track measurable progress while understanding the circumstances affecting an individual NSF Engine's performance.

The *Strategic and Implementation Plan (SIP)* is a forward-looking strategy for the Emergent phase of the award (project years three through five). Each NSF Engine starts development of the SIP in year one and completes it by the end of year two. The SIP is used by NSF to evaluate the NSF Engine for continued support beyond year two. The SIP sections include the following:

- (1) Vision, Mission, Goals and Measurable Metrics;
- (2) Research and Development;
- (3) Translation, including intellectual property strategy;
- (4) Workforce Development;
- (5) Economic Development;
- (6) Governance and Management;
- (7) Partnerships; and

(8) Project Evaluation.

The *Strategic Growth Plan* (SGP) builds upon the SIP and shifts the focus from early implementation to the NSF Engine's longer-term growth and sustainability. Beginning in year four, NSF Engines develop a forward-looking strategy for the Growth phase of the award, with additional planning refinement, and finalization occurring in year five. The SGP addresses:

(1) A strategy for establishing the RoS as a national leader in the NSF Engine's technology area(s);

(2) Strategies for attracting, creating, and supporting businesses in the region;

(3) Goals, strategies, milestones, and measures of progress for research and development, translation, workforce and economic development;

(4) A sustainability plan describing how the RoS will maintain and increase

economic growth beyond NSF funding; and

(5) Strategies for sustaining NSF Engine activities, programs, and other efforts important to continued research, translation, workforce development, and economic growth within the RoS.

Use of the Information: NSF uses the information from these four types of reports to monitor implementation and performance; assess progress toward established goals, milestones, and outcomes; identify risks and areas requiring attention; ensure compliance with award terms and conditions; and support program management, evaluation, and reporting to NSF leadership, the Administration, and Congress.

The reporting requirements also provide a consistent record of how each NSF Engine develops over time. The Quarterly Reports and ERT capture

ramp-up and ongoing implementation and performance to determine whether NSF Engines are advancing their proposed strategies and developing partnerships, capabilities, and resources needed to sustain their regional innovation ecosystems over time. The SIP and SGP provide details to NSF on each NSF Engine's forward-looking plans in order to make decisions about continued funding for the NSF Engine during phase transitions and establish the metrics that will be reported against in future ERTs.

Burden on the Public: The reporting requirements applicable to an individual NSF Engine vary based on its stage of development and year of the award. Table 1 summarizes each reporting component, the anticipated number of respondents and responses, and the estimated burden per response.

TABLE 1—REPORTING REQUIREMENTS AND ESTIMATED BURDEN PER RESPONSE

Reporting component	Number of NSF engines reporting	Number of responses per year	Minimum burden per response (hours)	Maximum burden per response (hours)	Respondent types
ERT Reports	21	2	10	20	NSF Engine CEO, Leadership team, Evaluation Lead, Communications Lead.
Quarterly Reports (only in year 1 of the new projects).	12	2	10	20	NSF Engine CEO, Leadership team, Evaluation Lead, Communications Lead.
Strategic and Implementation Plan (SIP).	12	1	Year 1: 40 Year 2: 50	Year 1: 80 Year 2: 100	NSF Engine CEO, Leadership team, Advisory entities.
Strategic Growth Plan (SGP)	21	1	Year 3: 5 Year 4: 50 Year 5: 100	Year 3: 10 Year 4: 150 Year 5: 120	NSF Engine CEO, Leadership team, Advisory entities.

Because the reporting requirements vary over the lifetime of an NSF Engine award, the burden estimates in Table 1 do not apply simultaneously to every NSF Engine. For example, a newly awarded NSF Engine would incur an estimated 80–160 hours of reporting burden in Year 1 for ERT Reports, Quarterly Reports, and SIP; 70–140 hours in Year 2 for ERT Reports and SIP; 25–50 hours in Year 3 for ERT Reports and SGP. This yields an estimated three-year total burden of 175–350 hours per each newly awarded Engine.

Dated: October 16, 2026.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2026–21461 Filed 10–19–26; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2027–10 and K2027–11; MC2027–11 and K2027–12; MC2027–12 and K2027–13]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <https://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT:

David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any,

can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. See 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

None. See Section III for summary proceedings.

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

III. Summary Proceeding(s)

1. *Docket No(s)*: MC2027–10 and K2027–11; *Filing Title*: USPS Request to Add New Mid-Market Standardized Distinct Product, PM–GA Contract 1111, and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 15, 2026; *Filing Authority*: 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

2. *Docket No(s)*: MC2027–11 and K2027–12; *Filing Title*: USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1112, and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 15, 2026; *Filing Authority*: 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

3. *Docket No(s)*: MC2027–12 and K2027–13; *Filing Title*: USPS Request to Add New Mid-Market Standardized Distinct Product, PM–GA Contract 1113, and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: October 15, 2026; *Filing Authority*: 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

This Notice will be published in the **Federal Register**.

Danielle LeFlore,

Legal Assistant.

[FR Doc. 2026–21421 Filed 10–19–26; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106675; File No. SR–FINRA–2026–004]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving a Proposed Rule Change, as Modified by Partial Amendment No. 1, To Amend FINRA Rule 2210 (Communications With the Public)

October 15, 2026.

I. Introduction

On February 10, 2026, the Financial Industry Regulatory Authority, Inc. (“FINRA”) filed with the Securities and Exchange Commission (“SEC” or “Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Exchange Act”) ¹ and Rule 19b–4 thereunder, ² a proposed rule change to amend FINRA Rule 2210 (Communications with the Public) to allow a member broker-dealer (“member”) to project performance or provide a targeted return with respect to

a security, a securities portfolio, or an asset allocation or other investment strategy in its communications with the public, subject to specified conditions.³

The proposed rule change was published for public comment in the **Federal Register** on February 25, 2026.⁴ The comment period closed on March 18, 2026. The Commission received comment letters in response to the Notice.⁵ On April 7, 2026, FINRA consented to extend until May 26, 2026, the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.⁶ On May 18, 2026, the Commission received a letter from FINRA stating, among other things, that it anticipated submitting a response to comments, as well as amendments to the proposed rule change.⁷ On May 20, 2026, the Commission published an order instituting proceedings to determine whether to approve or disapprove the proposed rule change (“OIP”).⁸ The Commission received comment letters in response to the OIP.⁹ On June 30, 2026, FINRA responded to the comment letters received in response to the Notice and OIP ¹⁰ and filed a partial amendment to the proposed rule change

³ See Exchange Act Release No. 104877 (Feb. 20, 2026), 91 FR 9308, 9313 (Feb. 25, 2026) (File No. SR–FINRA–2026–004) (“Notice”), <https://www.govinfo.gov/content/pkg/FR-2026-02-25/pdf/2026-03705.pdf>. FINRA stated that projections of performance “reflect an estimate of the future performance of an investment or investment strategy, which is often based on historical data and assumptions . . . [and] are commonly established through mathematical modeling,” and targeted returns “reflect the aspirational performance goals for an investment or investment strategy.” *Id.*

⁴ Notice.

⁵ The comment letters received in response to the Notice are available at <https://www.sec.gov/rules-regulations/public-comments/sr-fina-2026-004>.

⁶ See letter from Joseph Savage, Vice President and Associate General Counsel, Office of General Counsel, FINRA, dated Apr. 7, 2026, <https://www.finra.org/sites/default/files/2026-04/SR-FINRA-2026-004-Extension-5-26-2026.pdf>.

⁷ Letter from David Driscoll, Associate General Counsel, Office of General Counsel, FINRA, dated May 18, 2026 (“FINRA Response I”), <https://www.finra.org/sites/default/files/2026-05/SR-FINRA-2026-004-Response-to-Comments-20260518.pdf>.

⁸ See Exchange Act Release No. 105524 (May 20, 2026), 91 FR 30750 (May 26, 2026) (File No. SR–FINRA–2026–004), <https://www.govinfo.gov/content/pkg/FR-2026-05-26/pdf/2026-10365.pdf>.

⁹ The comment letters received in response to the OIP are available at <https://www.sec.gov/rules-regulations/public-comments/sr-fina-2026-004>.

¹⁰ See letter from Joseph Savage, Vice President and Associate General Counsel, Office of General Counsel, FINRA, dated Jun. 30, 2026 (“FINRA Response II”), <https://www.sec.gov/comments/SR-FINRA-2026-004/srfina2026004-913220-2799313.pdf>.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

(“Partial Amendment No. 1”).¹¹ The proposed rule change, as modified by Partial Amendment No. 1 (hereinafter referred to as the “proposed rule change” unless otherwise stated), was published for public comment in the **Federal Register** on July 7, 2026.¹² On July 21, 2026, FINRA consented to extend until October 23, 2026, the time period in which the Commission must approve or disapprove the proposed rule change.¹³ The Commission received comment letters in response to Notice II.¹⁴ On October 14, 2026, FINRA responded to the comment letters received in response to Notice II.¹⁵

This order approves the proposed rule change.

II. Description of the Proposed Rule Change

FINRA Rule 2210 generally prohibits communications with the public that predict or project performance.¹⁶ As discussed below, there are three exceptions to this general prohibition; the proposed rule change would create a fourth exception in limited circumstances.

A. FINRA Rule 2210 (Communications With the Public)

Among other things, FINRA Rule 2210 imposes restrictions on the content of a member’s communications with the public. For example, FINRA Rule

2210(d)(1) (General Standards) (hereinafter the “general content standards”) requires, among other things, that: (1) all member communications be based on principles of fair dealing and good faith, be fair and balanced, and provide a sound basis for evaluating the facts in regard to any particular security or type of security, industry, or service;¹⁷ and (2) the member: (a) not omit any material fact or qualification if the omission, in light of the context of the material presented, would cause the communication to be misleading;¹⁸ (b) not make any false, exaggerated, unwarranted, promissory, or misleading statement or claim in the communication;¹⁹ and (c) consider the nature of the audience to which the communication will be directed and provide details and explanations appropriate to the audience.²⁰

The general content standards also prohibit a communication prepared by a member from predicting or projecting performance, implying that past performance will recur, or making any exaggerated or unwarranted claim, opinion, or forecast.²¹ This general prohibition, however, does not apply to communications that contain: (1) certain hypothetical illustrations of mathematical principles;²² (2) certain investment analysis tools or written reports produced by such investment analysis tools;²³ and (3) certain price

targets contained in research reports on debt or equity securities.²⁴

B. The Proposed Rule Change

The proposed rule change would adopt a fourth exception to FINRA Rule 2210(d)(1)(F) to permit members’ communications to project performance or provide targeted returns with respect to a security, a securities portfolio, or an asset allocation or other investment strategy (hereinafter, “projected performance or targeted returns”), subject to the conditions described, in turn, below.²⁵

1. Written Policies and Procedures

The proposed rule change would require any member that communicates projected performance or targeted returns to adopt and implement written policies and procedures reasonably designed to ensure that the communication is relevant to the likely financial situation and investment objectives of the intended audience of the communication.²⁶ FINRA stated that, under such reasonably designed policies and procedures, a communication containing projected performance or targeted returns should only be distributed to investors whom a member reasonably believes have access to resources to independently analyze this information and who have the financial expertise to understand the risks and limitations of these types of presentations (referred to herein collectively as “investors who have the resources and financial expertise”).²⁷ FINRA stated that the proposed rule change generally would not permit the inclusion of projected performance or targeted returns in communications for

Investment Analysis Tools)). An “investment analysis tool” is “an interactive technological tool that produces simulations and statistical analyses that present the likelihood of various investment outcomes if certain investments are made or certain investment strategies or styles are undertaken, thereby serving as an additional resource to investors in the evaluation of the potential risks and returns of investment choices.” See FINRA Rule 2214(b).

²⁴ FINRA Rule 2210(d)(1)(F)(iii) (stating that a member may communicate a price target contained in a research report on debt or equity securities, provided that the price target has a reasonable basis, the report discloses the valuation methods used to determine the price target, and the price target is accompanied by disclosure concerning the risks that may impede achievement of the price target).

²⁵ Proposed FINRA Rule 2210(d)(1)(F)(iv).

²⁶ Proposed FINRA Rule 2210(d)(1)(F)(iv)(a).

²⁷ FINRA Response II at 10; FINRA Response III at 16; see Notice at 9310 (stating that a communication that contains projections of performance or targeted returns should only be distributed where the member reasonably believes the investors for whom that communication is intended have the financial expertise and resources to understand the risks and limitations of such presentations).

¹¹ Partial Amendment No. 1 is available on FINRA’s website at <https://www.finra.org/rules-guidance/rule-filings/sr-finra-2026-004>.

¹² See Exchange Act Release No. 105845 (Jul. 2, 2026), 91 FR 41723 (Jul. 7, 2026) (File No. SR-FINRA 2026-004) (“Notice II”), <https://www.govinfo.gov/content/pkg/FR-2026-07-07/pdf/2026-13713.pdf>.

¹³ Letter from Joseph Savage, Vice President and Associate General Counsel, Office of General Counsel, FINRA, dated Jul. 21, 2026, <https://www.finra.org/sites/default/files/2026-07/FINRA-2026-004-Extension2-20261023.pdf>.

¹⁴ The comment letters received in response to Notice II are available at <https://www.sec.gov/rules-regulations/public-comments/sr-finra-2026-004>.

¹⁵ See letter from Joseph Savage, Vice President and Associate General Counsel, Office of General Counsel, FINRA, dated October 14, 2026 (“FINRA Response III”), <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-1093079-3829368.pdf>.

¹⁶ See FINRA Rule 2210(d)(1)(F). FINRA interprets this prohibition to cover both projections of performance and targeted returns. Notice at 9309, 9310 n.29; see also FINRA Rule 2210 Frequently Asked Questions, Question D.7, <https://www.finra.org/rules-guidance/guidance/faqs/advertising-regulation> (“This prohibition [under Rule 2210(d)(1)(F)] extends to retail communications that include target returns to investors.”); FINRA Regulatory Notice 20-21 at 4 (Jul. 1, 2020), <https://www.finra.org/sites/default/files/2020-06/Regulatory-Notice-20-21.pdf> (stating that retail communications concerning private placements may not project or predict returns to investors such as yields, income, dividends, capital appreciation percentages or any other future investment performance).

¹⁷ FINRA Rule 2210(d)(1)(A).

¹⁸ *Id.*

¹⁹ FINRA Rule 2210(d)(1)(B).

²⁰ FINRA Rule 2210(d)(1)(E).

²¹ FINRA Rule 2210(d)(1)(F); but see, e.g., FINRA Rule 2215 (Communications with the Public Regarding Security Futures) (stating that members may include projected performance figures (including projected annualized rates of return) regarding securities futures products in communications subject to specified conditions enumerated in FINRA Rule 2215(b)(3)); FINRA Rule 2220 (Options Communications) (stating that members may include projected performance figures (including projected annualized rates of return) regarding options in communications subject to specified conditions enumerated in FINRA Rule 2220(d)(3)).

²² FINRA Rule 2210(d)(1)(F)(i) (stating that a member may communicate a hypothetical illustration of mathematical principles, provided that it does not predict or project the performance of an investment or investment strategy). FINRA stated that this exception applies to tools that serve the function of a calculator that computes the mathematical outcome of certain assumed variables without predicting the likelihood of either the assumed variables or the outcome (e.g., a calculator that computes a net amount of savings that an investor would earn over an assumed period of time with assumed variables of rates of returns, frequency of compounding, and tax rates). Notice at 9308.

²³ FINRA Rule 2210(d)(1)(F)(ii) (stating that a member may publish an investment analysis tool, or a written report produced by an investment analysis tool, that includes projections of performance provided it meets the requirements of FINRA Rule 2214 (Requirements for the Use of

a mass audience or intended for general circulation, including a general retail investor audience, as in such mass communications, a member generally could not form any expectation that the communication is relevant to the likely financial situation and investment objectives of the intended audience.²⁸ The proposed rule change would not, however, prescribe the ways in which a member may satisfy the policies and procedures requirement; rather, it would provide members with flexibility to develop policies and procedures that best suit their investor base and business models.²⁹ For example, FINRA stated that a member firm may wish to partly base its policies and procedures on its past experiences with particular types of investors who seek this information, group investors into categories or types, or restrict its intended audience to investors who have expressed interest or actually invested in particular types of securities.³⁰

2. Disclosure Requirements

The proposed rule change would impose two disclosure-related obligations. Specifically, as originally proposed in the Notice, the proposal would have required any member that communicates projected performance or targeted returns to provide sufficient information to enable the intended audience to understand: (1) the criteria used and assumptions made in calculating the projected performance or targeted return, including whether the projected performance or targeted return is net of anticipated fees and expenses;³¹ and (2) the risks and limitations of using the projected performance or targeted return in making investment decisions, including reasons why the projected performance or targeted return might differ from actual performance.³²

FINRA stated that the first prong of the disclosure requirement would not prescribe the methodology for calculating projected performance or targeted returns; rather, FINRA would expect that a member provide a general description of the methodology used sufficient to enable the intended audience to understand the basis for the

methodology, as well as the assumptions underlying the projection or targeted return.³³ FINRA stated that, absent this required disclosure, it would be more likely that a projection of performance or targeted return would mislead a potential investor.³⁴ FINRA also stated that the second prong of the proposed disclosure requirement would help ensure that investors do not unreasonably rely on a projected performance or targeted return given their uncertainty and risks.³⁵

In response to comments, however, FINRA amended the original proposal to remove from the first prong the proposed requirement that a member include in its disclosure whether its calculation of the projected performance or targeted return is net of anticipated fees and expenses,³⁶ and to remove from the second prong the proposed requirement that a member include in its disclosure reasons why the projected performance or targeted return might differ from actual performance.³⁷ FINRA stated that the general content standards, together with the proposed rule change's remaining disclosure requirements, would help ensure that investors receive the information necessary to consider the risks and limitations of such performance information.³⁸

3. Reasonable Basis Requirement; Recordkeeping Requirement

As originally proposed in the Notice, the proposal would have required any member that communicates projected performance or targeted returns to have a reasonable basis for the criteria used and assumptions made in calculating the projected performance or targeted return, and retain written records supporting the basis for such criteria and assumptions.³⁹ In response to comments, however, FINRA amended the original proposal to remove these requirements,⁴⁰ and instead proposed to amend the recordkeeping obligation under FINRA Rule 2210(b)(4)(A)(iv) to include information concerning the source of any projection of performance or targeted return used in the communication.⁴¹ As discussed further

below, FINRA stated that an express reasonable basis requirement is unnecessary because FINRA Rule 2210's existing general content standards would preclude the communication of unreasonable performance projections or targeted returns.⁴² FINRA also stated that the proposed recordkeeping requirement would be consistent with the other types of records currently required to be maintained pursuant to FINRA Rule 2210(b)(4) and would help regulators to evaluate members' compliance with the terms of the proposed rule change.⁴³

III. Discussion and Commission Findings

After careful review of the proposed rule change, comment letters received, and FINRA's response to the comments, the Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder that are applicable to a national securities association.⁴⁴ Specifically, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Exchange Act, which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.⁴⁵

The proposed rule change would create a new, reasonably tailored exception from FINRA Rule 2210's general prohibition on communications that predict or project performance. The proposed rule change would allow members to communicate projected performance or targeted returns, subject to requirements reasonably designed to protect investors and the public interest. In particular, the proposed rule change would, among other things, require members to: (1) adopt and implement written policies and procedures reasonably designed to ensure that the communication is relevant to the likely financial situation and investment objectives of the intended audience; (2) provide sufficient information to enable the intended audience to understand: (a) the criteria used and assumptions made in calculating the projected performance or targeted return, and (b) the risks and limitations of using the projected performance or targeted return in

²⁸ Notice at 9310–9311.

²⁹ *Id.* at 9310.

³⁰ *Id.* However, FINRA stated that the fact that an investor would be interested in high returns would not, by itself, mean that the projected performance or targeted returns are relevant to the likely financial situation and investment objectives of the intended audience. *Id.* at 9310 n.32.

³¹ Notice at 9311–12 (describing then-proposed FINRA Rule 2210(d)(1)(F)(iv)(c)).

³² *Id.*

³³ *Id.* at 9311.

³⁴ *Id.*

³⁵ *Id.* at 9312.

³⁶ FINRA Response II at 14–15; Partial Amendment No. 1.

³⁷ FINRA Response II at 14–15; Partial Amendment No. 1.

³⁸ FINRA Response II at 15.

³⁹ Notice at 9311 (describing then-proposed FINRA Rule 2210(d)(1)(F)(iv)(b)).

⁴⁰ FINRA Response II at 12; Partial Amendment No. 1 at 5–6.

⁴¹ Proposed FINRA Rule 2210(b)(4)(A)(iv); Partial Amendment No. 1 at 7.

⁴² FINRA Response II at 12.

⁴³ See *id.* at 13; Partial Amendment No. 1 at 7.

⁴⁴ In approving this rule change, the Commission has considered the rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

⁴⁵ 15 U.S.C. 78o–3(b)(6).

making investment decisions; and (3) maintain records including information concerning the source of any projection of performance or targeted return used in their communications.

As explained in detail below, the proposed conditions would help ensure that such communications are provided only to an appropriate audience of investors who have the resources and financial expertise and that such communications are provided with disclosures designed to support informed investment decision making. Further, the existing general content standards—when coupled with the proposed rule change's conditions—should help ensure that communications including projected performance and targeted returns are fair, balanced, and not misleading. Accordingly, and as explained in more detail below, the Commission finds that the proposed rule change is consistent with Section 15A(b)(6) of the Exchange Act. The Commission addresses the proposed rule change's specific provisions, and any related comments, in turn.

A. Scope of the Proposed Exception to the General Prohibition on Communications That Predict or Project Performance

As described above, the proposed rule change would permit members to communicate projected performance or targeted returns under certain conditions.⁴⁶ FINRA stated that some of its members' customers, including institutional investors and other sophisticated investors, request projected performance or targeted returns to help them make informed investment decisions, but FINRA Rule 2210 currently prohibits members from providing such information.⁴⁷ FINRA stated that, on the other hand, investors can obtain such performance information from other market participants, including registered investment advisers,⁴⁸ unregistered

intermediaries, and issuers.⁴⁹ FINRA stated that such different regulatory treatment can: (1) incentivize issuers to avoid offering securities through registered broker-dealers,⁵⁰ and (2) cause investor confusion because investors may receive different types of information about the same investments depending on the financial professional with whom they engage.⁵¹ For these reasons, FINRA stated that an additional exception to the general prohibition on projecting or predicting performance in member communications is warranted.⁵²

A number of commenters supported the proposed rule change.⁵³ These

portfolio or to the investment advisory services with regard to securities offered in the advertisement. 17 CFR 275.206(4)–(e)(8)(i). FINRA's proposed rule change would cover a subset of the types of hypothetical performance information covered by the IA Marketing Rule. Notice at 9313. FINRA stated that its proposed rule change would treat the communication of projected performance and targeted returns in a manner generally consistent with the IA Marketing Rule. *Id.*

⁴⁹ *Id.* at 9309, 9314.

⁵⁰ *Id.* at 9314.

⁵¹ *Id.* at 9309.

⁵² *Id.*

⁵³ See, e.g., letter from Eversheds Sutherland (US) LLP on behalf of the Committee of Annuity Insurers, dated Mar. 18, 2026, at 2, <https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-729427-2273554.pdf> (“CAI”); letter from Gail Bernstein, General Counsel and Head of Public Policy, Investment Adviser Association, dated Mar. 17, 2026, at 1–2, <https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-727988-2271277.pdf> (“IAA I”); letter from Bernstein, dated July 28, 2026, at 2, <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-978559-3059528.pdf> (“IAA II”); letter from James Dowd, CEO, North Capital Private Securities, dated Feb. 27, 2026, at 1, <https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-716827-2243174.pdf> (“North Capital I”); letter from Matthew Thornton (“Thornton”), Deputy General Counsel, Investment Company Institute, dated Mar. 18, 2026, at 1, <https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-728827-2272714.pdf> (“ICI I”); letter from Thornton, dated July 28, 2026, at 1–2, <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-978400-3059006.pdf> (“ICI II”); letter from Anya Coverman, President & CEO, Institute for Portfolio Alternatives, dated Mar. 18, 2026, at 1–2, <https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-729209-2273154.pdf> (“IPA”); letter from Bernard Canepa (“Canepa”), Managing Director & Associate General Counsel, SIFMA, dated Mar. 18, 2026, at 1, https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-729367-2273454_0.pdf (“SIFMA I”); letter from Canepa, dated July 27, 2026, <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-976199-3052947.pdf> (“SIFMA II”); letter from Simpson Thacher & Bartlett LLP, dated Mar. 18, 2026, at 1, <https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-728847-2272814.pdf> (“Simpson Thacher”); letter from Craig Pfeiffer, President and CEO, Money Management Institute, dated Mar. 18, 2026, at 1, <https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-730027-2274754.pdf> (“MMI”); letter from Jennifer Han, Chief Legal officer and Head of Global Regulatory Affairs, Managed Funds Association, dated Mar. 20, 2026, at 1, <https://www.sec.gov/>

commenters stated that the proposed rule change would help investors make more informed investment decisions,⁵⁴ reduce investor confusion,⁵⁵ remove an incentive for issuers to avoid using broker-dealers to distribute their offerings,⁵⁶ encourage capital formation,⁵⁷ and promote regulatory harmonization by aligning more closely with the IA Marketing Rule.⁵⁸

Other commenters opposed the proposed rule change.⁵⁹ One of these

[comments/sr-fina-2026-004/srfinra2026004-731447-2276834.pdf](https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-731447-2276834.pdf) (“MFA I”); letter from Han, dated June 16, 2026 at 1–2, <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-831639-2543984.pdf> (“MFA II”); letter from Catherine Bowman, Chair of the Alternative & Direct Investment Securities Association Legislative and Regulatory Committee, ADISA, dated July 28, 2026 at 1–2, <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-979180-3061748.pdf> (“ADISA”).

⁵⁴ See, e.g., IPA at 1 (stating that “[i]nvestors could use this information to consider alternative investment strategies, compare that information with projections and targeted returns from other entities, and make more informed investment decisions.”); CAI at 2; Simpson Thacher at 1–2; see MMI at 1.

⁵⁵ See, e.g., IPA at 2 (stating that the proposed rule change would help eliminate investor confusion caused by receiving different types of performance information on the same investment from both registered investment advisers and registered broker-dealers); Simpson Thacher at 1–2; MMI at 1; CAI at 2; IAA I at 2; IAA II at 2.

⁵⁶ See, e.g., IPA at 2 (stating that the proposed rule change would remove an incentive for issuers to distribute private offerings outside of the broker-dealer channel); see also MMI at 1 (stating that the proposed rule change would help address competitive disparities between investment advisers and broker-dealers).

⁵⁷ See, e.g., IPA at 2; Simpson Thacher at 1–2.

⁵⁸ See, e.g., IAA I at 2 (alignment will reduce compliance costs by permitting members to leverage existing compliance infrastructure developed to satisfy the IA Marketing Rule); IAA II at 2; MFA I at 1; CAI at 2; ICI I at 6; Simpson Thacher at 1–2; MMI at 1.

⁵⁹ See, e.g., letter from Michael Bixby, President, Public Investors Advocate Bar Association, dated Jul. 24, 2026, at 1, <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-973979-3030989.pdf> (“PIABA”); letter from “Average Civilian,” dated August 6, 2026, https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-994460-3111826_0_1.html (“Average Civilian”); letter from Marni Rock Gibson, President, NASAA, dated Mar. 18, 2026, at 2, <https://www.sec.gov/comments/sr-fina-2026-004/srfinra2026004-728987-2272934.pdf> (“NASAA”) (stating that NASAA cannot support the proposed rule change “without better investor protection guardrails incorporated into the text of the rule”). One commenter stated that FINRA has not created an administrative record sufficient to support approval of the proposed rule change, asserting that broker-dealer compliance costs associated with the proposed rule change would disproportionately impact capital formation for small issuers. Letter from James Hunter Poole (“Poole”), Executive Chairman & CEO, Obelisk Tech Systems Inc., dated May 27, 2026, https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-2395866_0.htm (“Obelisk I”); letter from Poole, dated July 22, 2026, <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-3014166.htm> (“Obelisk II”). In response, FINRA stated that the proposed rule

⁴⁶ Proposed FINRA Rule 2210(d)(1)(F)(iv).

⁴⁷ See Notice at 9309.

⁴⁸ Among other things, the Commission's Investment Adviser Marketing Rule (“IA Marketing Rule”) addresses the use of gross performance, net performance, related performance, extracted performance, hypothetical performance, and predecessor performance. See 17 CFR 275.206(4)–1(d). For purposes of the IA Marketing Rule, the term “hypothetical performance” means “performance results that were not actually achieved by any portfolio of the investment adviser.” 17 CFR 275.206(4)–1(e)(8). It includes but is not limited to: (1) performance derived from model portfolios; (2) performance that is backtested by the application of a strategy to data from prior time periods when the strategy was not actually used during those time periods; and (3) targeted or projected performance returns with respect to any

commenters stated that the proposed rule change would expose investors to substantial risk of misleading and unbalanced sales presentations;⁶⁰ another commenter stated that the proposed rule change would weaken FINRA Rule 2210 and is not in the public interest.⁶¹

Other commenters recommended various modifications to the scope of information covered by the proposed rule change. Several commenters requested that FINRA broaden the scope of information excepted.⁶² In particular, some commenters recommended modifications to further align the scope of information covered with the IA Marketing Rule.⁶³ One of these commenters recommended that FINRA amend the proposed rule change to permit the communication of all types of hypothetical performance.⁶⁴ Alternatively, this commenter recommended that, at a minimum, FINRA permit members to communicate certain types of hypothetical performance, including extracts from composites, composites of extracts, or track records developed based on the aggregation of actual positions across

change “does not impose unreasonable costs in terms of compliance or operations, including in connection with small issuer offerings facilitated by broker-dealers.” FINRA Response III at 12. The proposed rule change does not impose an additional mandatory compliance cost on all members; rather, it permits members—at their discretion—to communicate projected performance and targeted return information subject to conditions reasonably designed to protect investors and the public interest. Moreover, the record for this filing is based, in part, on years of FINRA engagement with its members, advisory committees, and the public, and it includes an Economic Impact Assessment addressing anticipated costs, benefits, and considered alternatives to best achieve its regulatory objectives. *See, e.g.*, Notice at 9309, 9315–17. As outlined in this order, and based on the record, FINRA met its burden to demonstrate the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder that are applicable to a national securities association.

⁶⁰ *See, e.g.*, PIABA at 2 (stating that members’ concerns over a competitive disadvantage with investment advisers must not take precedence over investor protection).

⁶¹ *See, e.g.*, letter from Honey J. Music, dated Jul. 28, 2026, <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-3060407.htm> (“Music”); *see* Average Civilian.

⁶² *See, e.g.*, SIFMA I at 1; Simpson Thacher at 3–4; letter from Molly Diggins, Partner & General Counsel, Monument Group, Inc. dated Mar. 18, 2026, at 2–3, <https://www.sec.gov/comments/sr-finra-2026-004/srfinra2026004-730507-2275274.pdf> (“Monument Group”); IAA I at 3–5; IAA II at 2–3.

⁶³ *See, e.g.*, SIFMA I at 1 (stating that incomplete alignment between FINRA Rule 2210 and the IA Marketing Rule results in uneven access to information about the same investment strategies depending solely on the regulatory channel through which the communication is delivered); Simpson Thacher at 3–4; Monument Group at 2–3; IAA I at 3–5; IAA II at 2–3.

⁶⁴ *See* IAA I at 3–5; IAA II at 2–3.

various accounts and/or funds.⁶⁵ Commenters similarly recommended that FINRA permit members to communicate backtested and model performance,⁶⁶ related performance,⁶⁷ and extracted performance.⁶⁸

One commenter requested that FINRA create a tiered regulatory framework that covers projected performance and targeted returns as well as educational, distribution, and cash-flow illustrations and imposes varying levels of restrictions on each category of communication.⁶⁹ One commenter recommended that FINRA remove targeted returns from the proposed rule change, stating that targeted returns should not have been covered by FINRA Rule 2210’s prohibition in the first place and therefore should not be subject to the proposed rule change.⁷⁰ Another commenter requested that FINRA create “a proportionate framework that recognizes the difference between a generalized target return and a detailed projection.”⁷¹

Commenters also requested that FINRA provide guidance on the application or impact of the proposed rule change under specific circumstances, such as the presentation of portfolio or investment characteristics,⁷² the presentation of

⁶⁵ IAA I at 5–6; IAA II at 3. IAA stated that these forms of performance are “derived from actual investment decisions and outcomes and do not present a meaningful risk of investor misunderstanding if subject to the same controls and conditions that FINRA proposes to apply” to projections of performance and targeted returns. IAA II at 3. In the context of the IA Marketing Rule, the Commission has stated that “performance that is extracted from a composite from multiple portfolios . . . may not reflect the holdings of any actual investor. As a result, . . . this performance information is subject to the additional protections that apply to advertisements containing hypothetical performance” Investment Adviser Marketing, Investment Advisers Act Release No. 5653 (Dec. 22, 2020), 86 FR 13024, 13077 (Mar. 5, 2021) (“IA Marketing Rule Adopting Release”).

⁶⁶ MFA I at 2; MFA II at 2; IAA I at 3–5; MMI at 2–4; Monument Group at 2–3; SIFMA I at 3–4 (backtested performance); ICI I at 6; *see* letter from Justine Tobin, Executive Representative & Founder, Tobin & Company Securities, dated Mar. 18, 2026, at 6, <https://www.sec.gov/comments/sr-finra-2026-004/srfinra2026004-729071-2272956.pdf> (“Tobin”) (the proposed rule change should permit broker-dealers to “provide financial projections and models to investors,” subject to certain disclosures).

⁶⁷ MFA I at 3–4; MFA II at 3–4; SIFMA I at 3–4; Simpson Thacher at 3–4; ICI I at 6–7; ICI II at 3.

⁶⁸ IAA I at 5–6; IAA II at 3; MMI at 4; *see* MFA I at 4; MFA II at 4.

⁶⁹ ADISA at 2–3.

⁷⁰ North Capital I at 1–3; letter from James Dowd, Chief Executive Officer, North Capital Private Securities, dated Jun. 2, 2026, at 1–2 (“North Capital II”), <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-799019-2416666.pdf>.

⁷¹ MMI at 4–5.

⁷² Simpson Thacher at 4.

gross versus net-of-fees performance,⁷³ and the presentation of internal rates of return.⁷⁴

In response to commenters who opposed the proposed rule change, FINRA stated that the investor protection requirements specific to the proposed rule change, including the policies and procedures requirements and the disclosure obligations, provide appropriate investor protection.⁷⁵ Because these proposed conditions would operate alongside the existing general content standards, FINRA stated that the proposed rule change would not reduce investor protection.⁷⁶

With respect to requests to modify the scope of communications covered by the proposed rule change, FINRA declined to amend the proposed rule change. In particular, FINRA declined to remove “targeted returns” from its scope or subject projected performance and targeted returns to different obligations, stating that FINRA continues to believe that investors may not always understand or appreciate the distinction between projected performance and targeted returns, so the same conditions should apply to these communications under FINRA Rule 2210.⁷⁷ FINRA also stated that it has long taken the position that Rule 2210(d)(1)(F) prohibits communications that contain targeted returns.⁷⁸

In addition, FINRA declined to modify the proposed rule change to cover additional types of performance at this time, stating that requests to do so are beyond the scope of the proposed rule change.⁷⁹ FINRA stated that the proposed rule change represents an incremental change, declined to address the merits of the requests to broaden the scope of the information covered, and noted that this does not foreclose future potential amendments to adopt standards for other performance categories.⁸⁰

FINRA also declined the request to create a tiered regulatory framework that would also address educational,

⁷³ *Id.*

⁷⁴ IAA I at 6–7; IAA II at 3; MMI at 7; MFA I at 6; MFA II at 6; Simpson Thacher at 2–3; Monument Group at 3.

⁷⁵ FINRA Response III at 19–20.

⁷⁶ *See, e.g., id.* at 9–10.

⁷⁷ FINRA Response II at 14; *see* Notice at 9310 n.29.

⁷⁸ FINRA Response III at 13 (citing FINRA Rule 2210 Frequently Asked Questions, Question D.7, *supra* n.16).

⁷⁹ FINRA Response II at 6; FINRA Response III at 4; *see* Notice at 9315 (stating FINRA believes that the proposed rule change strikes the right balance between protecting investors and allowing more information to be communicated to an appropriate audience).

⁸⁰ FINRA Response III at 4.

distribution, and cash-flow illustrations.⁸¹ FINRA stated that such a framework would require unnecessary categorization, definitional distinctions, and differing regulatory treatment that would create burdens and complexity that could frustrate members' understanding of and compliance with the proposed rule change.⁸² Finally, FINRA acknowledged commenters' requests for guidance, and stated that, if the Commission approves the proposed rule change, it will consider providing additional guidance as appropriate.⁸³

The proposed rule change reasonably expands the exceptions to FINRA's prohibition on communications that predict or project performance to cover projected performance and targeted returns in certain narrowly defined circumstances and subject to conditions that are reasonably designed to protect investors. As described in detail below, the proposed rule change is reasonably designed to help ensure that such communications are: (1) relevant to the likely financial situation and investment objectives of the intended audience (*i.e.*, investors who have the resources and financial expertise); and (2) made with disclosures that would equip the intended audience to evaluate the risks and limitations of such information.⁸⁴ In addition, the proposed rule change would require members to maintain records concerning the source of any projection of performance or targeted return used in the communication.⁸⁵

Currently, other market participants, including issuers and investment advisers, can provide projected performance and targeted returns to investors, subject to certain conditions. Because FINRA Rule 2210 prohibits members from communicating projected performance or targeted return information, certain investors may be confused by the different information they may receive about the same investment from different market participants. The proposed rule change would help to reduce this confusion—subject to conditions designed to protect investors, as discussed further below—by permitting investors to receive additional information and make more informed investment decisions.

Furthermore, by limiting the exception to projections of performance and targeted returns (and not expanding to include at this time additional categories of performance information

suggested by commenters, such as backtested, model, related, and extracted performance), the proposed rule change incrementally permits members to disseminate additional categories of performance information, while allowing FINRA to gain regulatory experience with its members' provision of projected performance and targeted return information to investors to evaluate whether future changes, including expansion of the exception, would be appropriate. FINRA stated that it would not foreclose the possibility of future amendments to address additional categories of performance information, and that it would consider providing additional guidance on the application of the proposed rule change to certain categories of information, as appropriate, if the Commission approves the proposed rule change.

It is likewise reasonable to subject projected performance and targeted returns to the same requirements, as this treatment is consistent with how FINRA has interpreted the general prohibition on predicting or projecting performance and recognizes that the distinction between targeted returns and performance projections is not always clear to investors.

For these reasons, the proposed rule change is reasonably 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.

B. Conditions of the Proposed Exception

As described above, the proposed rule change would allow members to communicate projected performance or targeted returns, subject to conditions reasonably designed to protect investors and the public interest. As originally proposed in the Notice, the proposal would have required members to: (1) adopt and implement written policies and procedures reasonably designed to ensure that the communication is relevant to the likely financial situation and investment objectives of the intended audience of the communication;⁸⁶ (2) provide sufficient information to enable the intended audience to understand: (a) the criteria used and assumptions made in calculating the projected performance or targeted return, including whether the projected performance or targeted return is net of anticipated fees and expenses;⁸⁷ and (b) the risks and limitations of using the projected performance or targeted return in

making investment decisions, including reasons why the projected performance or targeted return might differ from actual performance;⁸⁸ and (3) have a reasonable basis for the criteria used and assumptions made in calculating the projected performance or targeted return, and retain written records supporting the basis for such criteria and assumptions (“reasonable basis requirement”).⁸⁹

As discussed in more detail below, the Commission received comments on each of these proposed conditions, as well as other comments suggesting additional conditions or different requirements altogether. In response, FINRA determined to amend the proposed rule change to modify the disclosure requirements, remove the reasonable basis requirement, and impose a modified recordkeeping requirement.⁹⁰

1. Written Policies and Procedures

The proposed rule change would require any member that provides a communication containing projected performance or targeted returns with respect to a security, a securities portfolio, or an asset allocation or other investment strategy to adopt and implement written policies and procedures reasonably designed to ensure that the communication is relevant to the likely financial situation and investment objectives of the intended audience of the communication.⁹¹ FINRA stated that this condition is intended to provide members with the flexibility to develop policies and procedures that best suit their investor base and the business in which they engage.⁹² Nevertheless, FINRA stated that, under such reasonably designed policies and procedures, a communication that contains projected performance or targeted return information should only be distributed where the member reasonably believes that the intended audience has the resources and financial expertise.⁹³ FINRA also stated that the

⁸⁸ *Id.*

⁸⁹ *Id.* at 9311.

⁹⁰ See Partial Amendment No. 1.

⁹¹ Proposed Rule 2210(d)(1)(F)(iv)(a). FINRA stated that, to the extent a member makes this determination with respect to a retail customer and communicates projected performance or targeted returns with a recommendation of a securities transaction or investment strategy involving securities, Regulation Best Interest would apply. Notice at 9311.

⁹² *Id.* at 9310.

⁹³ See *id.* (discussing the written policies and procedures requirement); FINRA Response III at 16. As a result, FINRA stated that, in practice, it “expects that the proposed rule change will primarily impact institutional and other

⁸¹ *Id.* at 4–5.

⁸² *Id.* at 4.

⁸³ FINRA Response II at 16; FINRA Response III at 6.

⁸⁴ Proposed Rule 2210(d)(1)(F)(iv).

⁸⁵ Proposed Rule 2210(b)(4)(A)(iv).

⁸⁶ Proposed FINRA Rule 2210(d)(1)(F)(iv)(a).

⁸⁷ Notice at 9311–12.

proposed rule change generally would not permit a member to include projected performance or targeted returns in communications directed to a mass audience or intended for general circulation, including to a general retail investor audience, because a member generally could not form any expectation that the communication is relevant to the likely financial situation and investment objectives of the intended audience.⁹⁴

One commenter stated that the proposed policies and procedures requirement and the proposed disclosure requirement, combined with the existing investor protection obligations in the general content standards would ensure that investors are adequately informed and protected.⁹⁵

Two commenters recommended modifications to the proposed policies procedures requirement.⁹⁶ One commenter recommended that FINRA amend proposed FINRA Rule 2210(d)(1)(F)(iv)(a) to expressly require that a member's written policies and procedures be reasonably designed to ensure that a communication's intended audience possesses the financial expertise and resources to understand the risks and limitations of projected performance or targeted returns.⁹⁷ The commenter stated that given projected performance or targeted return information could be provided to retail investors, members should be expressly obligated to ensure that the intended audience has the resources and expertise to evaluate the information properly, and this modification would help ensure that members carefully consider the intended audience and not engage in direct marketing to certain investors.⁹⁸

By contrast, the other commenter appeared to request the removal of the policies and procedures requirement, stating that the proposed rule change's conditions discourage the communication of projected performance and targeted return information altogether.⁹⁹ This commenter recommended that FINRA amend the proposed rule change to permit the communication of such information to any investor "provided

that the assumptions underlying the projections are disclosed and appropriate cautionary language explains their limitations."¹⁰⁰

Several other commenters suggested that FINRA provide additional guidance regarding the policies and procedures requirement and the intended audience of the communications.¹⁰¹ One commenter requested that FINRA clarify that the proposed rule change would not require members to adopt policies and procedures reasonably designed to ensure that the investors who receive the communication have a mandated level of financial expertise and resources, as such a requirement would be "impractical and unwarranted."¹⁰² Another commenter stated that the proposed policies and procedures requirement would be redundant of the suitability requirements under FINRA Rule 2111(b) to the extent a communication is simultaneously subject to those requirements, and that satisfaction of institutional suitability obligations under FINRA Rule 2111(b) should automatically fulfill the proposed rule change's policies and procedures requirement.¹⁰³

In response to the request to modify the rule text to expressly provide that a member's policies and procedures must be reasonably designed to ensure the intended audience possesses the financial expertise and resources to understand the risks and limitations of the projected performance or targeted return, FINRA stated that the proposed rule change takes a similar approach to the one the Commission adopted in the IA Marketing Rule.¹⁰⁴ Specifically, FINRA observed that the IA Marketing Rule requires investment advisers communicating hypothetical performance information in an advertisement to "[a]dopt[] and implement[] policies and procedures reasonably designed to ensure that the hypothetical performance is relevant to the likely financial situation and investment objectives of the intended audience of the advertisement."¹⁰⁵ FINRA observed that, in the adopting release for the IA Marketing Rule, the Commission stated that this policies and procedures requirement was designed to help ensure that an adviser provides advertisements containing hypothetical performance information only to those investors who have the resources and

financial expertise to appropriately consider such information, and that hypothetical performance "may not be relevant to the likely financial situation and investment objectives of and may be misleading for investors that do not have the resources and financial expertise" and "could tell [such] an investor little."¹⁰⁶

FINRA stated that the proposed policies and procedures requirement would impose comparable obligations on members that intend to distribute communications that contain projected performance or targeted returns by limiting the distribution of such communications to investors who have the resources and financial expertise.¹⁰⁷ Providing such information to investors who do not have such resources and expertise, FINRA stated, "could be misleading as such persons may not understand the risks and limitations of relying on such presentations."¹⁰⁸ Accordingly, FINRA declined to modify as suggested.¹⁰⁹

FINRA also addressed the commenter's assertion that this proposed requirement would be duplicative of existing obligations under FINRA Rule 2111(b).¹¹⁰ FINRA stated that the proposed rule change would apply to all communications (not just those made to institutional customers) and would not be limited to those made in connection with, a recommendation.¹¹¹ However, to the extent a member wishes to adopt overlapping policies and procedures for compliance with both FINRA Rule 2111(b) and the proposed rule change, FINRA stated that a member may do so, as long as such policies and procedures address the requirements of each rule.¹¹²

It is reasonable to require members communicating projected performance or targeted returns to adopt and implement written policies and procedures reasonably designed to ensure that such communications are relevant to the likely financial situation and investment objectives of the intended audience of the communication.¹¹³ The proposed rule

sophisticated investors and those members that serve them." Notice at 9316.

⁹⁴ *Id.* at 9310–9311.

⁹⁵ ICI I at 5–6.

⁹⁶ NASAA at 2, 4–5; Tobin at 6.

⁹⁷ NASAA at 4–5.

⁹⁸ *Id.* at 5.

⁹⁹ Tobin at 1–2, 6 (stating that the conditions of the proposed rule change impose a level of supervisory responsibility that would make members reluctant to rely on it).

¹⁰⁰ *Id.* at 6.

¹⁰¹ *See, e.g.*, IPA at 2; Monument Group at 4–5.

¹⁰² IPA at 2.

¹⁰³ Monument Group at 4–5.

¹⁰⁴ *See* FINRA Response II at 8–9; FINRA Response III at 15–17.

¹⁰⁵ *See* FINRA Response III at 15 (citing 17 CFR 275.206(4)–1(d)(6)(i)).

¹⁰⁶ FINRA Response III at 16–17 (quoting IA Marketing Rule Adopting Release at 13083).

¹⁰⁷ *Id.* at 17.

¹⁰⁸ *Id.*

¹⁰⁹ FINRA Response II at 8; FINRA Response III at 15–16.

¹¹⁰ FINRA Response II at 9; FINRA Response III at 17–18.

¹¹¹ *See* FINRA Response II at 9.

¹¹² *See* FINRA Response III at 18.

¹¹³ The proposed rule change would, as a practical matter, not permit the inclusion of projected performance or targeted returns in communications to a mass audience or for general

change provides for flexibility in a member's development of such policies and procedures, which would allow members to account for their investor base and business models, while also requiring that the policies and procedures impose appropriate constraints on the audience that can receive such communications. Notably, this policies and procedures requirement generally would not permit the inclusion of projected performance for a mass audience or general circulation (including to a general retail audience) and is designed to help ensure that communications containing projected performance and targeted return information are only be distributed where the member reasonably believes that the intended audience has the resources and financial expertise.¹¹⁴ As a result, FINRA expects that such communications will primarily be distributed to institutional and other sophisticated investors. Further, this approach, including the related interpretations, is generally consistent with the Commission's interpretation of the IA Marketing Rule, thereby fostering greater regulatory uniformity, as appropriate, between the investor protections that apply when broker-dealers and investment advisers provide communications containing projected performance and targeted return information.

Similarly, while there may be some overlap in the obligations imposed by the proposed policies and procedures requirement and existing suitability obligations under FINRA Rule 2111(b), given that the rules serve different purposes, it is reasonable to maintain the separate obligations and not expressly provide that satisfaction of FINRA Rule 2111(b) would satisfy the proposed rule change. Nevertheless, a member seeking compliance efficiencies could adopt dual-use policies and procedures that address the requirements of both the proposed rule change and FINRA Rule 2111(b).

For these reasons, the proposed rule change is reasonably 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.

circulation, including to a general retail investor audience, because a member generally could not form any expectation that the communication is relevant to the likely financial situation and investment objectives of the intended audience in such situations. See Notice at 9310–11.

¹¹⁴ See FINRA Response II at 10; FINRA Response III at 16.

2. Disclosure Requirements

As originally proposed in the Notice, the proposal would have required any member communicating projected performance or targeted returns with respect to a security, a securities portfolio, or an asset allocation or other investment strategy to provide sufficient information to enable the intended audience to understand: (1) the criteria used and assumptions made in calculating the projected performance or targeted return, including whether the projected performance or targeted return is net of anticipated fees and expenses; and (2) the risks and limitations of using the projected performance or targeted return in making investment decisions, including reasons why the projected performance or targeted return might differ from actual performance.¹¹⁵

Two commenters recommended that FINRA modify the proposal as originally proposed in the Notice to more closely align the proposed disclosure requirements with those of the IA Marketing Rule.¹¹⁶ One of these commenters recommended that FINRA remove the requirement to disclose the reasons why the projected performance or targeted return information may differ from actual performance.¹¹⁷ This commenter stated that the IA Marketing Rule does not impose such a requirement, so the inclusion of this requirement would disadvantage broker-dealers by requiring them to provide more disclosures than investment advisers.¹¹⁸ The other commenter requested that FINRA confirm that members could satisfy the requirement to disclose the reasons why projected performance or targeted return information may differ from actual performance by using “standard or generic risk disclosure language addressing market risk, model risk, assumption uncertainty, and the inherent limitations of forward-looking statements.”¹¹⁹ This commenter also requested that FINRA confirm that disclosures prepared in compliance with the IA Marketing Rule would satisfy the proposed disclosure requirements of the proposed rule change.¹²⁰

¹¹⁵ Notice at 9311–12 (describing then-proposed FINRA Rule 2210(d)(1)(F)(iv)(c)).

¹¹⁶ SIFMA I at 3; MMI at 6 (stating that differences in the disclosure requirements under the proposed rule change and the IA Marketing Rule would create operational complexity for dual-registrants and members distributing adviser-prepared materials).

¹¹⁷ SIFMA I at 3.

¹¹⁸ *Id.*

¹¹⁹ MMI at 6.

¹²⁰ *Id.*

In response, FINRA amended the proposed rule change to remove the express requirements to disclose “whether the projected performance or targeted return is net of anticipated fees and expenses” and the “reasons why the projected performance or targeted return might differ from actual performance.”¹²¹ FINRA stated that the general content standards may, depending on the facts and circumstances, require members to include the disclosures that were removed from the initially proposed rule text to ensure that a communication containing a projection of performance or targeted return is fair, balanced, and not misleading.¹²² FINRA further stated that the general content standards, together with the proposed rule change's remaining disclosure requirements, would help ensure that investors receive the information necessary to consider the risks and limitations of performance information.¹²³ Separately, FINRA stated that, notwithstanding similar phrasing in the IA Marketing Rule and the proposed rule change, the phrasing is not identical and investment advisers are subject to a separate regulatory regime that may inform distinct regulatory treatment based on the facts and circumstances.¹²⁴ For this reason, at this time, FINRA cannot categorically conclude that disclosures that comply with the IA Marketing Rule would always satisfy the requirements of FINRA Rule 2210.¹²⁵

Commenters generally supported these amendments.¹²⁶ Other commenters opposed the elimination of the proposed express requirements to disclose “whether the projected performance or targeted return is net of anticipated fees and expenses” and the “reasons why the projected performance or targeted return might differ from actual performance.”¹²⁷ One of these commenters stated that if the general content standards already require the same disclosures, then an express requirement would have placed no additional compliance burden on members; if, however, a situation arises in which making these disclosures imposes a heavier compliance burden on a member, then the investors “absolutely should” receive such

¹²¹ FINRA Response II at 15; Partial Amendment No. 1 at 8.

¹²² Partial Amendment No. 1 at 8.

¹²³ FINRA Response II at 15.

¹²⁴ FINRA Response III at 13.

¹²⁵ *Id.*

¹²⁶ See, e.g., ADISA at 5–6; IAA II at 2; SIFMA II at 1; ICI II at 2.

¹²⁷ See, e.g., PIABA at 3; Average Civilian at 1.

disclosures.¹²⁸ Another commenter stated that investors could be easily misled without disclosures about fees, risks, and why projections might differ from actual performance.¹²⁹

In response, FINRA declined to reintroduce these express disclosure requirements, stating that nothing in the proposed rule change would deprive investors of material information or reduce investor protection.¹³⁰ FINRA stated that the general content standards, which would apply to all communications of projected performance or targeted return information, already prohibit the omission of any material fact or qualification if the omission, in light of the context of the material presented, would cause the communication to be misleading.¹³¹ FINRA further explained that whether a communication that contains a projected performance or targeted return includes sufficient disclosure to meet the obligations in the proposed rule change and the general content standards will depend on the facts and circumstances of the presentation, including the intended audience receiving the communication.¹³²

Specifically, FINRA stated that while it would generally expect that, to meet the disclosure requirement regarding the criteria used and assumptions made, a communication would provide sufficient information for the investor to determine whether a projected performance or targeted return is net of anticipated fees and expenses,¹³³ the contours of this disclosure would depend on the facts and circumstances, including for example, the sophistication of the intended audience.¹³⁴ Similarly, FINRA stated that, to comply with the requirement to disclose the risks and limitations, FINRA would generally expect that a communication that presents a projection of performance or targeted return to provide sufficient information to enable the investor to understand the reasons why the projected performance or targeted return may differ from actual performance.¹³⁵ FINRA noted, however, that these disclosures could be tailored to the intended audience.¹³⁶ Ultimately, FINRA stated that the amended

disclosure requirements retain the essential elements of the initial proposed rule change, while also providing appropriate flexibility for members to tailor their communications based on the specific communication and its intended audience.¹³⁷

Accordingly, FINRA concluded that the proposed rule change, in combination with the general content standards, will ensure that investors have sufficient information to consider the risks and limitations of relying on such performance projections.¹³⁸

The proposed rule change reasonably requires FINRA members communicating projected performance or targeted returns to provide sufficient information to enable the intended audience to understand: (1) the criteria used and assumptions made in calculating the projected performance or targeted return; and (2) the risks and limitations of using the projected performance or targeted return in making investment decisions. Instead of prescribing the specific content of the required disclosures, the proposed rule change would permit members to tailor the disclosures to their intended audience, consistent with the requirements under the proposed rules, the general content standards, and the federal securities laws. In this way, the proposed rule change appropriately recognizes that the specific disclosures required for each communication of projected performance or targeted return information will depend on, among other things, the projected performance or targeted return information itself, the audience of the communication, and the nature of the security, securities portfolio, or asset allocation or other investment strategy at issue.¹³⁹ Accordingly, while it is expected that a member would need to disclose whether a projected performance or targeted return is net of anticipated fees and expenses and/or the reasons why the projected performance or targeted return might differ from actual performance to meet the disclosure requirements under the proposed rule, the proposed rule change would provide members flexibility to tailor such communications where appropriate depending on the facts and circumstances, including for example, the particulars of the specific

communication and the intended audience.

Further, these disclosure requirements would supplement FINRA Rule 2210's existing general content standards, which broadly require, among other things, that member communications, including communications containing a projection of performance or targeted return, are fair and balanced, and prohibit the omission of any material fact or qualification if the omission, in light of the context of the material presented, would cause the communication to be misleading.¹⁴⁰ As a result, the proposed disclosure requirements, together with the general content standards, should help ensure that investors receive sufficient information to understand the criteria, assumptions, risks, and limitations associated with the projected performance or targeted returns.¹⁴¹

For these reasons, the proposed rule change is reasonably 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.

3. Reasonable Basis Requirement; Recordkeeping Requirement

As originally proposed in the Notice, the proposal included a reasonable basis requirement, which would have required any member that provides a communication containing projected performance or targeted returns with respect to a security, a securities portfolio, or an asset allocation or other investment strategy to have "a reasonable basis for the criteria used and assumptions made in calculating the projected performance or targeted return, and retain[] written records supporting the basis for such criteria and assumptions."¹⁴² In response to commenters' recommendations to remove, replace, refine, or further explain this requirement,¹⁴³ FINRA

¹⁴⁰ FINRA Rule 2210(d)(1).

¹⁴¹ Because the proposed rule change would impose upon members specified disclosure obligations that operate alongside the general content standards, and these obligations are separate from those that the IA Marketing Rule imposes upon investment advisers, it is reasonable that disclosures made in compliance with the IA Marketing Rule would not automatically satisfy the disclosure requirements of FINRA Rule 2210.

¹⁴² Notice at 9311 (describing then-proposed FINRA Rule 2210(d)(1)(F)(iv)(b)).

¹⁴³ See, e.g., SIFMA I at 2–3 (stating, among other things, that third-party projections complicate the application of the reasonable basis requirement and members making recommendations are already subject to Regulation Best Interest, which requires a reasonable basis to believe that a recommendation is in the best interest of a retail customer based on

Continued

¹²⁸ PIABA at 3.

¹²⁹ Average Civilian at 1.

¹³⁰ FINRA Response II at 15; FINRA Response III at 10.

¹³¹ FINRA Response II at 15 (citing FINRA Rule 2210(d)(1)(A)).

¹³² FINRA Response III at 10.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.* at 10–11.

¹³⁷ FINRA Response III at 10.

¹³⁸ *Id.* at 11.

¹³⁹ For similar reasons, FINRA reasonably declined to opine that any disclosures that comply with the IA Marketing Rule would necessarily comply with the disclosure requirements of the proposed rule change. *Id.* at 13.

amended the proposed rule change to remove it.¹⁴⁴ Instead, FINRA proposed to amend FINRA Rule 2210(b)(4) to require that members maintain records concerning the source of any performance projection or targeted return used in their communications.¹⁴⁵

FINRA stated that an express reasonable basis requirement is unnecessary because FINRA Rule 2210's existing general content standards would preclude any unreasonable performance projections or targeted returns.¹⁴⁶ Specifically, FINRA stated that the general content standards already require, among other things, that all member communications be based on principles of fair dealing and good faith; be fair and balanced; and not make any false, exaggerated, unwarranted, promissory, or misleading statement, claim, opinion, or forecast.¹⁴⁷ FINRA stated that under these applicable standards, it has not identified a set of facts where a projection of performance or targeted return lacking a reasonable basis could comply with FINRA requirements.¹⁴⁸

To the extent a member communicates projected performance or targeted return information sourced from third parties, FINRA further stated that it would expect members to continue to meet the requirements of the general content standards and reminded members that these standards prohibit them from, for example, publishing or circulating any communication that the member knows, or has reason to know, contains any untrue statement of material fact or is otherwise false or misleading.¹⁴⁹ FINRA explained that the level of due diligence necessary to assess presentations of performance

calculated by third parties would depend on the facts and circumstances.¹⁵⁰ While FINRA would not generally expect a member to independently verify all of the criteria and assumptions underlying the calculation of a projection prepared by a third party, it would expect a member to evaluate the source of such information, assess whether the available information in the projection is supported, and satisfy itself that the presentation meets the general content standards of Rule 2210.¹⁵¹ Moreover, members would also need to consider the availability of information from the third party and whether such information would be necessary for the member to satisfy its obligations under Rule 2210.¹⁵²

FINRA also stated that amending the proposed rule change to require members to keep records concerning the source of any projections and targeted returns will help substantiate the basis for such performance presentations.¹⁵³

Some commenters supported the removal of the reasonable basis requirement from the proposed rule change and the addition of the new recordkeeping requirement.¹⁵⁴ Two of these commenters stated that eliminating the reasonable basis requirement would align the proposed rule change more closely with the IA Marketing Rule, thereby permitting dual registrants to reduce compliance costs by leveraging existing compliance infrastructure developed for the IA Marketing Rule.¹⁵⁵ One commenter also stated that the general content standards would have made the reasonable basis requirement unnecessary and duplicative.¹⁵⁶ One supportive commenter requested that FINRA provide guidance on what would constitute reasonable assumptions and acceptable methodologies for the calculation of projected performance or targeted return information.¹⁵⁷

One commenter opposed FINRA's removal of the reasonable basis requirement, stating that FINRA Rule 2210 already imposes an independent reasonable basis requirement in other contexts notwithstanding the existence of the general content standards.¹⁵⁸ This

commenter also stated that if the general content standards effectively impose a reasonable basis requirement on members, an express requirement would have placed no additional compliance burden on members.¹⁵⁹ This commenter further stated that even if a situation arises in which an express reasonable basis requirement imposes a heavier compliance burden, then it is precisely the burden the member should carry for the protection of investors.¹⁶⁰ This commenter also opposed the removal of the recordkeeping requirement embedded in the reasonable basis requirement, stating that it would effectively preclude regulators and investors from testing the fairness and reasonableness of such projections.¹⁶¹

In response, FINRA reiterated that it was unable to identify a set of facts where a projection of performance or targeted return lacking a reasonable basis could comply with FINRA Rule 2210's existing general content standards, and so accordingly, it does not believe that investor protection is reduced by removing the reasonable basis requirement.¹⁶² Moreover, FINRA stated that: (1) the proposed recordkeeping requirement—coupled with the existing requirement that member communications provide a sound basis for evaluating the facts in regard to any particular security or type of security—would require members to substantiate the basis for such performance presentations in order to demonstrate compliance with the content standards;¹⁶³ and (2) in most cases, members would be unable to demonstrate compliance with the proposed rule change and the general content standards without records to support the basis for the criteria used and assumptions made in calculating a projection of performance or targeted return.¹⁶⁴ For these reasons, FINRA stated that the proposed recordkeeping requirement and the general content standards provide robust investor protection.¹⁶⁵ Furthermore, FINRA stated that the omission of an express reasonable basis requirement and the inclusion of other conditions similar to those in the IA Marketing Rule would reduce compliance uncertainty for member personnel who act both as

an understanding of the risks, rewards, and costs associated with the investment); ICI I at 5–6 (stating, among other things, that FINRA Rules 2210(d)(1)(A) and (B), as well as the proposed “policies and procedures” and “disclosure” rules, would ensure that investors are adequately informed and protected); Monument Group at 4 (stating, among other things, that the reasonable basis requirements would unnecessarily burden member with onerous and duplicative due diligence and recordkeeping requirements in connection with marketing private funds); MFA I at 4–6 (stating that requiring broker-dealers to independently rederive a third-party adviser's IA Marketing Rule-compliant targeted returns and projected performance would not benefit investors); MMI at 5–8 (requesting practical guidance on the application of the reasonable basis requirement to, among other things, adviser-prepared materials, including materials prepared in compliance with the IA Marketing Rule).

¹⁴⁴ FINRA Response II at 12; Partial Amendment No. 1 at 5–7.

¹⁴⁵ FINRA Response II at 12–13; Partial Amendment No. 1 at 7.

¹⁴⁶ FINRA Response II at 12.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 13.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.* at 12–13.

¹⁵⁴ *See, e.g.,* SIFMA II at 1; ICI II at 1–2; *see also* IAA II at 2.

¹⁵⁵ IAA II at 2; *see* ICI II at 2.

¹⁵⁶ ICI II at 2.

¹⁵⁷ ADISA at 4–5.

¹⁵⁸ PIABA at 2 (stating that there is a reasonable basis requirement for price targets (FINRA Rule 2210(d)(1)(F)), communications including a

recommendation of securities (FINRA Rule 2210(d)(7)), and recommendations in public appearances including a recommendation of securities (FINRA Rule 2210(f)(2))).

¹⁵⁹ *Id.* at 2–3.

¹⁶⁰ *Id.* at 3.

¹⁶¹ *Id.*

¹⁶² FINRA Response III at 8.

¹⁶³ *Id.* at 9 (citing FINRA Rule 2210(d)(1)(A)).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

registered representatives and investment adviser representatives, as well as for members that are either dually registered as investment advisers or distribute communications containing projections or targeted returns that are available to both member customers and advisory clients.¹⁶⁶ For these reasons, FINRA declined to reintroduce the reasonable basis requirement into the proposed rule change.¹⁶⁷

With respect to requests for guidance on the reasonableness of specific assumptions used to calculate projected performance or targeted returns, FINRA stated that the long-established content standards in current FINRA Rule 2210 provide sufficient principles for members to assess the reasonableness of the criteria used and assumptions made in a projection of performance or targeted return.¹⁶⁸ FINRA added that whether a projection of performance or targeted return is reasonable under these general content standards will depend on the facts and circumstances of the presentation.¹⁶⁹ Finally, FINRA indicated that if the Commission approves the proposed rule change, it will consider what additional guidance may be warranted.¹⁷⁰

It is reasonable to remove the reasonable basis requirement from the proposed rule change and to require members to maintain records concerning the source of any performance projection or targeted return used in their communications. The general content standards—combined with the recordkeeping requirement—effectively require members to substantiate the basis of any performance projection or targeted return prior to communicating it to investors, as it would be difficult for a member to demonstrate compliance with the proposed rule change and the general content standards without records supporting the basis for the criteria used and assumptions made in calculating the projected performance or targeted return information.¹⁷¹ Under these circumstances, an express reasonable basis requirement would be duplicative of the general content standards.

For these reasons, the proposed rule change is reasonably 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.

4. Other Comments

A number of commenters recommended other changes to the proposed rule change, including additional conditions or alternative approaches altogether, as well as the inclusion of compliance safe harbors.

With respect to additional conditions, one commenter recommended that—to the extent a member communicates projected performance or targeted return information to retail customers—FINRA amend the proposed rule change to limit such communications to those made in support of, or in connection with, a recommendation of any securities transaction or investment strategy involving securities (including account recommendations) that is subject to Regulation Best Interest.¹⁷² FINRA declined to make this change, stating that the general content standards and the conditions of the proposed rule change provide appropriate investor protection to retail investors in the absence of a recommendation covered by Regulation Best Interest.¹⁷³ FINRA reiterated that under the proposed policies and procedures requirement, communications containing projected performance or targeted returns should only be distributed to investors who have the resources and financial expertise,¹⁷⁴ and could not be included in communications directed to a mass audience or for general circulation, including a general retail investor audience.¹⁷⁵

It is reasonable that the proposed rule change does not limit a member's ability to communicate projected performance or targeted returns to retail investors to only those circumstances where the communications are made in support of, or in connection with, a recommendation subject to Regulation Best Interest. As discussed above, the proposed policies and procedures requirement is designed to limit communications containing projected performance or targeted returns to investors who have the resources and financial expertise. In addition, the proposed rule change would impose disclosure obligations that require FINRA's members to provide sufficient information to enable the intended audience to understand the criteria, assumptions, risks, and limitations associated with such information. Taken

together with the general content standards of FINRA Rule 2210, these requirements both limit the scope of retail investors who would be eligible to receive these communications to those who are in a position to understand these communications and their associated limitations and would help ensure that any retail investor who receives such a communication would have the information to evaluate it.

With respect to commenters that recommended alternative approaches, one commenter requested that FINRA subject capital acquisition brokers ("CABs") and non-CAB members to the same or similar rules related to the communication of projected performance and targeted return information about unregistered securities to institutional investors.¹⁷⁶ A second commenter requested that FINRA regulate the use of registered index-linked annuity ("RILA") illustrations in a manner similar to variable annuity communications pursuant to FINRA Rule 2211 (Communications with the Public About Variable Life Insurance and Variable Annuities).¹⁷⁷ In both instances, FINRA declined to do so. FINRA stated that CABs are subject to a separate rulebook that is specifically limited to firms that elect to operate as CABs with specified limitations on their activities.¹⁷⁸ Accordingly, FINRA disagreed that the communication standards designed for the limited activities of a CAB would be appropriate for a non-CAB member under FINRA Rule 2210.¹⁷⁹ FINRA also stated that to the extent the commenter was requesting an amendment to FINRA Rule 2211, such a request is outside the scope of the proposed rule change.¹⁸⁰

It is reasonable to impose different regulatory obligations on CAB and non-CAB members related to the communication of projected performance or targeted returns to institutional investors about unregistered securities. CABs are subject to a separate FINRA rulebook that imposes more limited regulatory obligations that are commensurate with

¹⁷⁶ Monument Group at 5 (stating that if the Commission approves the proposed rule change, two different standards would apply even where both types of broker-dealers market only unregistered securities to institutional investors).

¹⁷⁷ CAI at 2.

¹⁷⁸ FINRA Response III at 13.

¹⁷⁹ See *id.*

¹⁸⁰ See FINRA Response II at 17. FINRA also stated that a member could not generally form an expectation that a communication to a mass audience is relevant to the likely financial situation and investment objectives of the intended audience, and whether a RILA illustration intended for a mass audience contains a performance projection or targeted return will depend on the facts and circumstances. *Id.*

¹⁶⁶ *Id.* at 8.

¹⁶⁷ *Id.* at 7–11.

¹⁶⁸ *Id.* at 5.

¹⁶⁹ *Id.* at 5–6.

¹⁷⁰ *Id.* at 6.

¹⁷¹ *Id.* at 9.

¹⁷² NASAA at 5–6.

¹⁷³ FINRA Response III at 19.

¹⁷⁴ FINRA Response II at 10; FINRA Response III at 16.

¹⁷⁵ FINRA Response III at 19; see Notice at 9310–11.

their limited activities. For that reason, communication rules that are designed for a CAB's limited business model are inappropriate for non-CAB members that may engage in more expansive business activities. Similarly, the imposition of FINRA Rule 2210's additional restrictions upon CABs would tend to erode the regulatory benefit that the more limited CAB rulebook was designed to provide to members who limit their activities and elect CAB status. In addition, it is reasonable not to amend FINRA Rule 2211 as part of the proposed rule change given it is outside the scope of the proposal.

Another commenter recommended—based on requirements in the Uniform Prudent Investor Act (“UPIA”)—that FINRA require the communication of multiple possible outcomes “as an array of probability in different economic conditions” based on statistical norms instead of a single performance projection or targeted return.¹⁸¹ In response, FINRA stated that the UPIA is a model law that establishes general standards for trustee conduct when investing trust property, and therefore FINRA does not believe that proposed rule change is appropriate for application of the model law.¹⁸² FINRA acknowledged that the provision of multiple possible outcomes may be valuable in some instances but declined to require in every instance that members provide projections of performance or targeted returns in a specific manner or that such presentations be based on specific, differing market conditions.¹⁸³ FINRA stated that the disclosures required under the proposed rule change would provide sufficient information to investors and would also provide members flexibility to tailor their communications based on the intended audience of the communication.¹⁸⁴

It is reasonable that the proposed rule change does not require the disclosure of multiple possible outcomes, as recommended by the commenter. The proposed rule change and the general content standards impose a principles-based framework for the content of member communications containing projected performance or targeted return information. For this reason, it is reasonable to expect that the members communicating projected performance

or targeted return information will present such information and any corresponding disclosures in a way that equips the intended audience to meaningfully understand its risks and limitations. Depending on the facts and circumstances, a member may wish to simultaneously provide multiple projections or targets, but FINRA Rule 2210 need not require such presentations in every circumstance.

Further, a commenter suggested that FINRA provide examples or safe harbors for the types of recipients to whom a communication of projected performance or targeted return could be sent under the proposed rule change, including a safe harbor that expressly permits dual registrants to use communications prepared in compliance with the IA Marketing Rule.¹⁸⁵ FINRA responded that it does not believe that it is necessary to provide any specific safe harbors or additional guidance at this time.¹⁸⁶ With respect to requests for safe harbors tied to the type of recipient, the methodologies used, or the disclosures made, FINRA stated that the proposed rule change is intended to provide members with the flexibility to develop policies and procedures that best suit their investor base and the business in which they engage (e.g., policies and procedures based in part on the member's past experiences with particular types of investors who seek this information).¹⁸⁷ For this reason, FINRA stated that whether a communication containing a projection of performance or a targeted return complies with FINRA Rule 2210 will depend on the facts and circumstances.¹⁸⁸ FINRA stated,

¹⁸⁵ MMI at 6–8 (stating that presumptively permissible audiences should include: (1) high-net-worth retail clients who have been individually assessed; (2) retail clients in managed account or advisory relationships who have completed investment profile questionnaires indicating a level of sophistication and risk tolerance; (3) retail clients meeting specified financial sophistication thresholds; (4) institutional investors; (5) qualified purchasers; and (6) certain accredited investors in Investment Company Act 3(c)(1) funds); *see* ADISA at 5 (requesting safe harbors “for firms that utilize standardized methodologies and prescribed disclosures”). Relatedly, another commenter requested that FINRA establish a “formal exemptive relief process” in which members can seek guidance on the permissible use of “different types of performance presentations and product illustrations.” CAI at 2. In response, FINRA stated that it perceives no need for such a process as part of this proposed rule change, as it would address types of performance that are beyond the scope of the proposed rule change. FINRA Response II at 16. It is reasonable to decline to establish an exemptive relief process, as the comment is outside the scope of the proposed rule change.

¹⁸⁶ *Id.* at 9, 16.

¹⁸⁷ FINRA Response III at 6.

¹⁸⁸ *Id.*

however, that if the Commission approves the proposed rule change, it will consider whether additional guidance or amendments would be appropriate.¹⁸⁹

The proposed rule change reasonably provides a principles-based approach for members to determine the appropriate audience for these communications. Eliminating this flexibility in favor of predefined categories or safe harbors would fail to account for the fact that the circumstances of each communication—including the nature of the communication; the security, securities portfolio, or asset allocation or other investment strategy at issue; and the nature of the intended audience—will be relevant to whether a particular communication would comply with this proposed rule change. As such, it is reasonable to decline to establish specific safe harbors based on categorical, *ex ante* classifications of investors eligible to receive projected performance or targeted return information.¹⁹⁰ FINRA also stated that if the Commission approves the proposed rule change, FINRA will consider whether guidance is needed in the future.¹⁹¹

For these reasons, the proposed rule change is reasonably 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.

IV. Conclusion

For the reasons set forth above, the Commission finds that the proposed rule change, as modified by Partial Amendment No. 1, is consistent with Section 15A(b)(6) of the Exchange Act, which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and, in general, protect investors and the public interest.¹⁹²

It is therefore ordered pursuant to Section 19(b)(2) of the Exchange Act¹⁹³ that the proposed rule change (SR–

¹⁸⁹ *Id.*

¹⁹⁰ For similar reasons, the proposed rule change reasonably does not include safe harbors for communications that include projections of performance or targeted returns that adhere to specific calculation methodologies or include specific disclosures. *See* ADISA at 5 (requesting safe harbors “for firms that utilize standardized methodologies and prescribed disclosures”).

¹⁹¹ *See* FINRA Response III at 6.

¹⁹² 15 U.S.C. 78o–3(b)(6).

¹⁹³ 15 U.S.C. 78s(b)(2).

¹⁸¹ Music at 1. Music stated “that the public is better served by adopting UPIA use” by advisers, “which always requires modern portfolio theory directly derived from statistical analysis as a process.” *Id.*

¹⁸² FINRA Response III at 7.

¹⁸³ *Id.*

¹⁸⁴ *Id.*

FINRA–2026–004) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹⁴

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–21393 Filed 10–19–26; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21968 and #21969; UTAH Disaster Number UT–20023]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Utah

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of the Presidential declaration of a major disaster for Public Assistance Only for the state of Utah (FEMA–4948–DR), dated October 7, 2026.

Incident: Cottonwood Fire, Flooding, and Mudslides.

DATES: Issued on October 7, 2026.

Incident Period: July 13, 2026 through July 24, 2026.

Physical Loan Application Deadline Date: December 7, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: July 7, 2027.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Jennifer Talarico, Office of Disaster Recovery, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given as a result of the President's major disaster declaration on October 7, 2026, Private Non-Profit organizations providing essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal <https://lending.sba.gov> or in person at other locally announced locations. For further assistance please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Beaver, Piute.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Private Non-Profit Organizations with Credit Available Elsewhere	3.625
Private Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 219686 and for economic injury is 219690.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026–21469 Filed 10–19–26; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21970 and #21971; NEW HAMPSHIRE Disaster Number NH–20017]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of New Hampshire

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of the Presidential declaration of a major disaster for Public Assistance Only for the state of New Hampshire (FEMA–4947–DR), dated October 7, 2026.

Incident: Severe Storm and Flooding.

DATES: Issued on October 7, 2026.

Incident Period: June 10, 2026 through June 11, 2026.

Physical Loan Application Deadline Date: December 7, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: July 7, 2027.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Milton Murphy, Office of Disaster Recovery, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given as a result of the President's major disaster declaration on October 7, 2026, Private Non-Profit organizations providing essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal <https://lending.sba.gov> or in person at other locally announced locations. For further assistance please contact the SBA disaster assistance customer service center by email at disastercustomerservice@sba.gov or by phone at 1–800–659–2955. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

The following areas have been determined to be adversely affected by the disaster:

Primary County: Carroll.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Private Non-Profit Organizations with Credit Available Elsewhere	3.625
Private Non-Profit Organizations without Credit Available Elsewhere	3.625
<i>For Economic Injury:</i>	
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 219706 and for economic injury is 219710.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026–21467 Filed 10–19–26; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice 13152]

60-Day Notice of Proposed Information Collection: National Contact Point Web Page

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection

¹⁹⁴ 17 CFR 200.30–3(a)(12).

from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *December 21, 2026*.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov*. You can search for the document by entering "Docket Number: DOS-2026-1157" in the Search field. Then click the "Comment Now" button and complete the comment form.

- *Email:* *usncp@state.gov*

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Alan Krill, who may be reached on *USNCP@state.gov*.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* National Contact Point Web Page.
 - *OMB Control Number:* None.
 - *Type of Request:* New Collection.
 - *Originating Office:* EEB/IFD/OIA.
 - *Form Number:* No form.
 - *Respondents:* Individuals or organizations submitting information as part of the Specific Instance Process under the OECD Guidelines for Multinational Enterprises on Responsible Business Conduct.
 - *Estimated Number of Respondents:* 180 per year.
 - *Estimated Number of Responses:* 180.
 - *Average Time per Response:* 20 minutes.
 - *Total Estimated Burden Time:* 60 hours.
 - *Frequency:* On occasion.
 - *Obligation to Respond:* Voluntary.
- We are soliciting public comments to permit the Department to:
- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
 - Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
 - Enhance the quality, utility, and clarity of the information to be collected.
 - Minimize the reporting burden on those who are to respond, including

through the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The information collected will be used by the U.S. National Contact Point (U.S. NCP) to administer the Specific Instance process under the OECD Guidelines for Multinational Enterprises on Responsible Business Conduct. The information enables the U.S. NCP to understand the issues raised by a submitter, determine whether a matter is eligible for further consideration, obtain relevant information from the parties, facilitate dialogue or mediation where appropriate, and prepare any resulting statements or recommendations. The information may also be used to communicate with the parties, manage the case, and support the U.S. NCP's reporting and other responsibilities under the OECD Guidelines. Especially due to a recent increase in the volume of inquiries and submissions to the NCP, the collection is necessary for the Department to evaluate and process Specific Instance submissions and efficiently and effectively carry out the U.S. NCP's Specific Instance functions.

Methodology

This collection will be completed totally online, through a dedicated web page.

Alice M. Kottmyer,

Attorney-Adviser, Office of the Legal Adviser, Department of State.

[FR Doc. 2026-21460 Filed 10-19-26; 8:45 am]

BILLING CODE 4710-07-P

DEPARTMENT OF STATE

[Public Notice:13150]

Determination and Certification With Respect to the Child Soldiers Prevention Act (CPSA) of 2008

Pursuant to section 404 of the CSPA (22 U.S.C.2370c-1) and presidential delegation of authority dated August 4, 2025, I hereby: Determine that it is in the national interest of the United States to waive in part the application of the prohibition in section 404(a) of the CSPA with respect to the Central African Republic to allow for the provision of international military

education and training (IMET) assistance and excess defense articles (EDA) and the issuance of direct commercial sales (DCS) licenses to the extent that the CSPA would restrict such assistance; to waive in part the application of the prohibition in section 404(a) of the CSPA with respect to the DRC to allow for the provision of IMET and peacekeeping operations (PKO) assistance, and the issuance of DCS licenses to the extent that the CSPA would restrict such assistance; to waive the application of the prohibition in section 404(a) of the CSPA with respect to Ethiopia; to waive the application of the prohibition in section 404(a) of the CSPA with respect to Nigeria; to waive in part the application of the prohibition in section 404(a) of the CSPA with respect to Somalia to allow for the provision of PKO assistance and support provided pursuant to 10 U.S.C. 331 and 10 U.S.C. 333 to the extent that the CSPA would restrict such assistance; to waive in part the application of the prohibition in section 404(a) of the CSPA with respect to Venezuela to allow for the provision of IMET assistance to the extent that the CSPA would restrict such assistance; to waive the application of the prohibition in section 404(a) of the CSPA with respect to Yemen; and to waive the application of the prohibition in section 404(a) of the CSPA to allow for the issuance of DCS licenses related to other U.S. government assistance for the above countries and, with respect to the Russian Federation, solely for the issuance of DCS licenses in connection with the International Space Station.

I certify that the governments of the above countries are taking effective and continuing steps to address the problem of child soldiers.

Accordingly, I hereby waive such applications of section 404(a) of the CSPA.

This determination and certification shall be published in the **Federal Register** and shall be transmitted, along with the accompanying Memorandum of Justification, to Congress.

Dated: September 30, 2026.

Marco Rubio,

Secretary of State, U.S. Department of State.

[FR Doc. 2026-21394 Filed 10-19-26; 8:45 am]

BILLING CODE 4710-05-P

DEPARTMENT OF STATE

[Delegation of Authority No. 629]

Title: Delegation of Authority to the Office of Presidential Appointments

ACTION: Notice.

SUMMARY: On August 11, 2026, the Under Secretary of State for Management signed a delegation of authority to the Director and Deputy Director of the Office of Presidential Appointments, as set out below.

DATES: The Under Secretary for Management signed the delegation of authority on August 11, 2029.

FOR FURTHER INFORMATION CONTACT:

Alice Kottmyer, Attorney-Adviser, L/M, 202-679-8083, kottmyeram@state.gov.

SUPPLEMENTARY INFORMATION:

Delegation of Authorities and Functions Involving Administration of the Office of Presidential Appointments Programs

By virtue of the authority vested in me by the Secretary of State in Delegation of Authority 514, and to the extent authorized by law, I hereby delegate to the Director of the Office of Presidential Appointments (“the Director”), and the Deputy Director of the Office of Presidential Appointments (“the Deputy Director”) consistent with the duties of their office as outlined in the Foreign Affairs Manual and Foreign Affairs Handbook, the functions and authorities related to the programs, laws and regulations administered by or relating to the substantive specialty of the office as follows:

1. The authority to prescribe regulations and approve exceptions arising under laws administered by or relating to the programs of the Office of Presidential Appointments.

2. The authority to approve Minister-Counselor and Counselor diplomatic title exception requests where the lack of such title would constitute a major impairment to the effective performance of the member’s duties or the function of the mission.

3. The authority to approve accreditation of persons who are not U.S. government employees abroad (including U.S. government personal services contractors; commercial contractors performing business on behalf of the U.S. government; and grantees).

4. The role of Custodian of the Great Seal of the United States, including all functions related to the operation of the Great Seal and maintenance of the press.

Technical Provisions

The Secretary, Deputy Secretary, Deputy Secretary for Management and Resources, and the Under Secretary for Management, may at any time exercise the functions herein delegated.

Any actions related to the functions described herein that may have been taken prior to the date of this delegation of authority by the Office of Presidential

Appointments consistent with their duties as outlined in the Foreign Affairs Manual or Foreign Affairs Handbook, are hereby affirmed and ratified. Such actions shall remain in force as if taken under this delegation of authority, unless or until such actions are rescinded, amended, or superseded.

Any act, executive order, regulation, manual or procedure subject to, affected, or incorporated by, this delegation shall be deemed to be such act, executive order, regulation, manual or procedure as amended from time to time. As used in this delegation of authority, the word “function” includes any duty, obligation, power, authority, responsibility, right, privilege, discretion, or activity.

Signed on August 11, 2026, by Jason Evans, Under Secretary for Management.

(Authority: 22 U.S.C. 2651a.)

Alice M. Kottmyer,

Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State.

[FR Doc. 2026–21412 Filed 10–19–26; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2026–0100]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Grote Industries, LLC

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of availability of supplemental information; request for comments.

SUMMARY: This notice advises the public of new information that FMCSA believes is relevant to the application from Grote Industries, LLC (Grote) for an exemption from the requirement that exterior lighting devices on commercial motor vehicles (CMVs) be steady-burning. If granted, the exemption would allow motor carriers to operate CMVs equipped with auxiliary warning lamps controlled by Grote’s Rear-End Collision Warning (RCW) system. Following publication of the Agency’s notice seeking comment, Grote provided additional information to FMCSA staff concerning the design and operation of the RCW system, including the color and activation sequence of the auxiliary warning lamps, the interaction between the RCW and brake-activated warning functions, system operation on

combination vehicles, and the operation of the radar detection system. FMCSA is making this supplemental information available in the docket and provides an opportunity for public comment.

DATES: Comments must be received on or before November 19, 2026.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2026–0100 by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. See the Public Participation and Request for Comments section below for further information.

- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W58–213, West Building, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* 1200 New Jersey Avenue SE, W58–213, West Building, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* (202) 493–2251.

- Each submission must include the Agency name and the docket number (FMCSA–2026–0100) for this notice. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the Privacy Act heading below.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL–14 FDMS (Federal Docket Management System (FDMS)), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>. The comments are posted without edit and are searchable by the name of the submitter.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Chief, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, FMCSA; MCPSV@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages interested persons to participate in this proceeding by submitting comments and related materials regarding Grote’s supplemental information discussed in this notice.

A. Submitting Comments

If you submit a comment, please include the docket number for this

notice (FMCSA–2026–0100), indicate the specific section of this document to which the comment applies, and provide a reason for your suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to <https://www.regulations.gov/docket/FMCSA-2026-0100/document>, click on this notice, click “Comment,” and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

FMCSA will consider all comments and material received during the comment period. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable.

B. Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as “PROPIN” to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at brian.g.dahlin@dot.gov. At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

C. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, insert FMCSA–2026–0100 in the keyword box, select the document tab and choose the document to review. To view comments, click this notice, then click “Browse Comments.” If you do not have access to the internet, you may view the docket by visiting Dockets Operations in the DOT West Building, 1200 New Jersey Avenue SE, W58–213, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant’s safety analysis. The Agency must provide an opportunity for public comment on the request.

The Agency reviews the application, safety analyses, and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved absent such exemption, pursuant to the standard set forth in 49 U.S.C. 31315(b)(1). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision(s) from which the exempted party will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

On December 10, 2025, Grote submitted an application for a five-year exemption from 49 CFR 393.25(e), which generally requires exterior lamps on CMVs to be steady-burning. Grote requested the exemption on behalf of motor carriers seeking to use auxiliary warning lamps in conjunction with Grote’s RCW system. Grote’s application described one or more auxiliary lamps positioned on the rear or sides of a CMV or trailer. The application described a rear-facing radar system that calculates the time-to-collision (TTC) of vehicles

approaching from behind and also contemplated use of the system on the side of a CMV for side-impact protection during parking maneuvers.

In its application, Grote stated that the RCW signal circuit would activate when TTC was less than or equal to a threshold corresponding to a substantial risk of an impending collision, typically between 2.1 and 4.0 seconds. Grote proposed two possible auxiliary-lamp operating sequences. Under one sequence, red lamps would flash between four and sixteen times during a four-second period and then burn steady red while the RCW signal remained active. Under the alternative sequence, amber lamps would operate as SAE J595 Class 3 or Class 2 strobe lamps for up to four seconds and then burn steady red while the RCW signal remained active. Grote further stated that the auxiliary lamps could also be used in combination with brake and marker signal circuits.

On February 9, 2026, FMCSA published a notice of Grote’s application and requested public comment (91 FR 5798). The notice described the RCW system as activating the auxiliary lamps when a TTC threshold was reached and stated that, following the initial flashing or strobing sequence, the lamps would burn steady red while the collision risk persisted.

On March 4, 2026, FMCSA extended the comment period by 60 days, through May 10, 2026, after the Commercial Vehicle Safety Alliance requested additional time to review the application (91 FR 10674).

During the comment period, interested parties raised questions and concerns regarding, among other issues, the relationship between the proposed RCW system and forward collision warning technology, the meaning conveyed to following motorists by the auxiliary warning lamps, and the proposed transition from flashing or strobing warning lamps to a steady-burning red indication. CVSA expressed concern that following motorists could interpret steady-burning red lamps as an indication that the CMV was braking and recommended that the RCW system not transition from flashing amber to steady-burning red for a warning condition unrelated to brake application.

IV. Supplemental Information Provided by Grote

Following the close of the comment period, FMCSA staff sought clarification from Grote regarding the design and operation of the RCW system. FMCSA’s questions addressed the operation and sequencing of the auxiliary warning

lamps, the relationship between the RCW function and Grote's auxiliary brake-warning function, the priority between those functions when both are activated, installation on various CMV types and combinations, and operation of the radar detection system.

Grote subsequently provided the following supplemental information:

A. RCW Warning-Lamp Operation and Color

Grote clarified that when operating as part of the RCW system, the auxiliary warning lamps pulse in amber for up to four seconds with each activation of the RCW signal circuit and do not transition to a steady-burning red indication. Grote explained that the transition from amber pulsation to steady-burning red is associated with the brake-activated auxiliary pulsating lamp function, not the RCW warning function.

This supplemental information differs from the description in the original application and February 9, 2026, notice, which stated that after the initial flashing or strobing RCW warning sequence, the auxiliary lamps would transition to steady-burning red while the RCW signal remained active.

B. Functional Priority and Interaction With Auxiliary Brake-Activated Warning Lamps

Grote explained that the RCW system uses the same auxiliary lamps used by its brake-activated auxiliary pulsating lamp system.

When an RCW event and a braking event occur at the same time, Grote stated that the brake-activated function takes precedence over the RCW function. Thus, when the service brakes are applied during an RCW event, the auxiliary lamps would transition from the RCW warning sequence to the applicable brake-activated warning sequence. Any steady-burning red indication would therefore be associated with brake application rather than with the RCW warning function.

The original application stated generally that the RCW auxiliary lamps could be used in combination with brake and marker signal circuits but did not describe the operational priority between those functions. Grote's supplemental explanation provides additional information concerning that hierarchy.

C. Radar Detection and Activation

Grote stated that the RCW system uses a self-contained, rear-facing radar system capable of detecting approaching vehicles at distances of approximately 200 meters. The system continuously evaluates the relative motion of an

approaching vehicle and calculates TTC. When the calculated TTC reaches the programmed activation threshold, the RCW system automatically activates the auxiliary amber warning lamps.

Grote further stated that the RCW system does not require the CMV driver to activate or otherwise interact with the system and that operation of the RCW radar would not interfere with other radar-based vehicle detection systems.

D. Scope and Combination Vehicles

Grote clarified that it intends the requested exemption to apply to all CMVs. For combination vehicles consisting of more than one trailing unit, including doubles and triples, Grote stated that the RCW system would be installed and operated on the rear-most unit of the combination.

E. Supplemental Materials

FMCSA has placed in the docket a memorandum summarizing the meeting between FMCSA staff and Grote during which Grote provided the operational clarifications described above. The memorandum also includes a chart provided by Grote illustrating the operation of the RCW system and its interaction with the brake-activated auxiliary lamp function.

The memorandum to the docket is titled "Ex Parte Communication with Grote Industries, LLC Regarding Rear-End Collision Warning Lamp System."

V. Reopening of Comment Period and Request for Comments

FMCSA believes interested persons should have an opportunity to review and comment on this new information before the Agency makes a decision on Grote's exemption request. Comments submitted in response to this notice must be limited to addressing any relevant information summarized in this notice and in the Memorandum to the Docket identified above. Comments addressing other matters will not be considered by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2026-21390 Filed 10-19-26; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2008-0065]

Notice of Petition for Extension of Special Approval

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This document provides the public notice that the Maryland Department of Transportation Maryland Transit Administration MARC Train Service (MACZ), petitioned FRA to extend a special approval of an alternate standard for periodic brake equipment maintenance.

DATES: FRA must receive comments on the petition by December 21, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Steven Zuiderveen, Railroad Safety Specialist, FRA Motive Power & Equipment Division, telephone: 202-493-6337, email: steven.zuiderveen@dot.gov.

SUPPLEMENTARY INFORMATION: Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter dated April 27, 2026, MACZ petitioned FRA for an extension of a special approval of an alternate standard for periodic brake equipment maintenance per 49 CFR parts 229 (Railroad Locomotive Safety Standards) and 238 (Passenger Equipment Safety Standards). The relevant Docket Number is FRA-2008-0065.

Specifically, MACZ requests approval to continue applying alternate standards for the CCB-KE-3.9 air brake system of the MARC HHP-8 locomotive fleet. This alternate standard to 49 CFR 229.29(e), *Air brake system calibration, maintenance, and testing*, and 238.309(a)(2), *Periodic brake equipment maintenance—General*, allows for an increase in the level two and level three maintenance intervals to 2,944 days (8 years). MACZ explains that it continues

to maintain the air brake systems in accordance with the existing conditions of relief in this docket, and that it has realized a high level of reliability with the air brake system. Further, MACZ indicates that the locomotives are expected to continue in passenger service for MACZ, operated and maintained by Amtrak on the Northeast Corridor, for the foreseeable future.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by December 21, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to inform its processes. 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 <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2026-21448 Filed 10-19-26; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2026-2444]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This document provides the public notice that BNSF Railway Company (BNSF) petitioned FRA seeking approval to modify a signal system by removing fixed derails on a line segment protected by Positive Train Control (PTC).

DATES: FRA must receive comments on the petition by December 21, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Scott Johnson, Railroad Safety Specialist, FRA Signal, Train Control, and Crossings Division, telephone: 406-210-3608, email: scott.j.johnson@dot.gov.

SUPPLEMENTARY INFORMATION: Under part 235 of title 49 Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that by letter received July 10, 2026, BNSF petitioned FRA seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA-2026-2444.

Specifically, BNSF requests approval to remove fixed derails located in advance of the Fort Madison movable bridge on the Chillicothe Subdivision in Illinois. Fixed derails would be removed

from their interlockings on main tracks Nos. 1 and 2 between mileposts (MPs) 232.6 and 231.2. BNSF notes that PTC is fully operational in this area and "fulfills the safety overlay function previously fulfilled by the derails, ensuring that trains will always stop short of the raised bridge in the event the crew misses a signal." Therefore, BNSF states the fixed derails have become redundant and are a potential failure point.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by December 21, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. 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 <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2026-21389 Filed 10-19-26; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION**Federal Railroad Administration****[Docket Number FRA–2026–2707]****Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System****AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).**ACTION:** Notice.**SUMMARY:** This document provides the public notice that the Southeastern Pennsylvania Transportation Authority (SEPTA) petitioned FRA seeking approval to discontinue or modify a signal system.**DATES:** FRA must receive comments on the petition by December 21, 2026. FRA will consider comments received after that date to the extent practicable.**ADDRESSES:**

Comments: Comments related to this docket may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Scott Johnson, Railroad Safety Specialist, FRA Signal, Train Control, and Crossings Division, telephone: 406–210–3608, email: scott.j.johnson@dot.gov.

SUPPLEMENTARY INFORMATION: Under part 235 of title 49 Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that by letter received September 2, 2026, SEPTA petitioned FRA seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2026–2707.

Specifically, SEPTA requests to remove control point (CP) North Elwyn (milepost (MP) 14.60) on the West Chester Line, including signals 2N and 4N and automatic block signals 1461

and 1462. The subject area is located between Schuylkill Interlocking (MP 0.8) and Wawa Interlocking (MP 18.07) on main tracks Nos. 1 and 2. In the petition, SEPTA states that CP North Elwyn is “operationally redundant” due to service limit changes and infrastructure configuration. Further, SEPTA explains that removing the CP and automatic block signals will “simplify the signal system, reduce maintenance requirements, and maintain or improve overall system reliability.”

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by December 21, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA’s dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. 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 <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2026–21391 Filed 10–19–26; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION**Federal Railroad Administration****Federal Transit Administration****[Docket No. FRA–2026–2740]****Joint Application Package From the State of Utah to the Surface Transportation Project Delivery Program and Proposed Memorandum of Understanding (MOU) Assigning Environmental Responsibilities to the State****AGENCY:** Federal Railroad Administration (FRA), Federal Transit Administration (FTA), U.S. Department of Transportation (DOT).**ACTION:** Notice, request for comments.

SUMMARY: This notice announces that FRA and FTA (Agencies) have received and reviewed an application package from the State of Utah (State), Utah Department of Transportation (UDOT), requesting participation in the Surface Transportation Project Delivery Program (Program). Under the Program, the Agencies may assign, and a State may assume, responsibilities under the National Environmental Policy Act (NEPA), and all or part of the Agencies’ responsibilities for environmental review, consultation, or other actions required under any Federal environmental laws except certain statutory exclusions with respect to one or more railroad projects and one or more public transportation projects within the State. The Agencies have determined the application package to be complete and developed a draft Memorandum of Understanding (MOU) with the State outlining how UDOT will implement the Program with the Agencies’ oversight. The public is invited to comment on UDOT’s request, including its application package and the proposed MOU, which includes the proposed assignments and assumptions of environmental review, consultation, and other activities.

DATES: Comments must be received on or before November 19, 2026.

ADDRESSES: Comments related to Docket No. FRA–2026–2740 may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must refer to the Federal Railroad Administration, the Federal Transit Administration, and the docket number in this notice (FRA–2026–2740). Note that all submissions received, including any personal information provided, will be posted without change and will be

available to the public on <https://www.regulations.gov>. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000 (65 FR 19477), or at <https://www.transportation.gov/privacy>.

FOR FURTHER INFORMATION CONTACT:

For FRA: Ms. Geri Robinson, Senior Environmental Protection Specialist, Office of Environmental Program Management, Federal Railroad Administration, telephone: (202) 951-0710; email: Geri.Robinson@dot.gov.

For FTA: Mr. Jay Ciavarella, Division Chief, Office of Planning and Environment, telephone: (312) 353-1653, email: Jason.Ciavarella@dot.gov.

For UDOT: Ms. Carissa Watanabe, Environmental Program Manager, Utah Department of Transportation, telephone: (503) 939-2798; email: cwatanabe@utah.gov.

SUPPLEMENTARY INFORMATION:

Background

Section 327 of Title 23, United States Code (23 U.S.C. 327) establishes the Surface Transportation Project Delivery Program, also referred to as the NEPA Assignment Program (Program). It allows the Secretary of the U.S. Department of Transportation (Secretary) to assign, and a State to assume, responsibility for all or part of the Secretary's responsibilities for environmental review, consultation, or other actions required under the National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4370h) and any Federal environmental law with respect to one or more highway projects within the State, as well as one or more railroad, public transportation, and/or multimodal projects. FRA is authorized to act on behalf of the Secretary with respect to these matters for railroad projects and FTA is authorized to act on behalf of the Secretary with respect to these matters for public transportation projects.

The State of Utah initially participated in the Federal Highway Administration's (FHWA's) Program. In accordance with 23 U.S.C. 327, the NEPA Assignment Memorandum of Understanding (MOU) was executed between the State, acting through UDOT, and FHWA and became effective on January 17, 2017. After the initial MOU term, the agreement was renewed on May 26, 2022. Since being accepted into the FHWA NEPA Assignment Program, the State has successfully completed four audits, seven self-assessments, and one monitoring event. FHWA has consistently publicly stated that the State continues to meet all requirements of the NEPA Assignment

Program. The State will have participated in the Program for 10 years on December 17, 2027.

Pursuant to 23 CFR 773.107(b)(1) and (2), UDOT provided public notice of its draft joint application requesting FRA and FTA NEPA assignment responsibilities on July 29, 2026. It was available for a 30-day comment period, with comments due by the close of business on August 28, 2026. The notice was published in a statewide newspaper and is available at: <https://connect.udot.utah.gov/events/notice-of-availability-of-the-utah-department-of-transportations-application-to-assume-the-federal-railroad-administrations-and-federal-transit-administrations-nepa-responsi/>. UDOT also sent notice of the joint application by email and letter with request for comment to all transit agencies in Utah, metropolitan planning organizations, regional planning organizations, associations of governments, regulatory agencies, and Native American Tribes. UDOT notified State agencies through the State of Utah's Resource Development Coordination Council, which is responsible for notifying all State agencies and compiling any comments received related to actions that may affect the physical resources of the State. On September 3, 2026, UDOT formally submitted its joint application package to the Agencies. The submission includes a verification of Statewide notice and solicitation of public comment, Utah's determination that the State of Utah's Public Records Act is comparable to the Federal Freedom of Information Act, the draft MOU, and the UDOT Commissioner's signature approving the application.

Under the proposed MOU, the Agencies would assign to the State the responsibility for making decisions on railroad and public transportation projects as described in UDOT's application and in Part 2 of the draft MOU. As provided in subpart 2.3, UDOT is requesting to assume the Agencies' responsibilities under NEPA for the following covered classes of railroad and public transportation projects upon execution of the Program MOU with the Agencies: all railroad projects in Utah whose source of Federal funding comes from FRA or require FRA approvals; all public transportation projects in Utah whose source of Federal funding comes from FTA or requires FTA approvals; and all projects funded by other Federal agencies, or projects without any Federal funding, that also require FRA or FTA approvals. As provided in subparts 2.1.1 and 2.1.2, UDOT is requesting to assume the Agencies'

responsibilities under NEPA for these covered railroad and public transportation projects where UDOT is the Direct Recipient and responsible for the design (for FTA) or final design (for FRA) and construction of the project, or where UDOT is designated in a project-specific agreement as the project sponsor or co-sponsor. For these projects, UDOT requests to assume only the Agencies' NEPA responsibilities; the request does not include assuming the NEPA responsibilities of other Federal agencies. UDOT may assume the Agencies' responsibilities under NEPA for locally administered railroad or public transportation projects by mutual agreement between the State and FRA or FTA, as applicable, pursuant to the requirements of 23 U.S.C. 327(l). In addition, UDOT would establish appropriate relationships with other Operating Administration(s) involved in a multimodal project, including cooperating agency, participating agency, and lead or co-lead agency relationships under NEPA. Lastly, UDOT may rely on other Federal agencies' NEPA analyses consistent with NEPA, USDOT, FRA and FTA regulations, policies, and guidance, as applicable. UDOT's assumption of these NEPA Assignment responsibilities will provide for the highest degree of program-wide consistency and efficiency in document review and agency coordination. It will also provide the greatest opportunity for streamlining benefits.

Excluded from assignment are the following:

(1) Railroad or public transportation projects that cross State boundaries or that cross or are adjacent to international boundaries. For purposes of the State's application and the proposed MOU, a project is considered "adjacent to international boundaries" if it requires the issuance of a new, or modification of an existing, Presidential Permit.

(2) As provided at 23 U.S.C. 327(a)(2)(D), any railroad or public transportation project that is not assumed by the State as identified in the State's application and under subparts 2.3 through 2.6 of the proposed MOU, remains the responsibility of FRA or FTA.

Under the proposed MOU, UDOT would also assume the responsibility to conduct the following environmental review, reevaluation, consultation, or other action pertaining to the review or approval of railroad and public transportation projects specified under MOU subpart 2.3 and required under the following Federal environmental laws and executive orders related to

railroad and public transportation projects:

Environmental Review Process

Efficient environmental reviews for project decisionmaking and One Federal Decision, 23 U.S.C. 139
Planning and Environmental Linkages, 23 U.S.C. 168, except for FHWA and FTA responsibilities associated with 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304
Programmatic Mitigation Plans, 23 U.S.C. 169, except for FHWA and FTA responsibilities associated with 23 U.S.C. 134 and 135 and 49 U.S.C. 5303 and 5304
Efficient environmental reviews, 49 U.S.C. 24201
General provisions, 49 U.S.C. 5323
Environmental Impact and Related Procedures, 23 CFR part 771

Air Quality

Clean Air Act (CAA), 42 U.S.C. 7401–7671q, with the exception of any general conformity determinations

Noise

Noise Control Act of 1972, 42 U.S.C. 4901–4918

Wildlife

Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531–1544
Fish and Wildlife Coordination Act, 16 U.S.C. 661–667d
Bald and Golden Eagle Protection Act, 16 U.S.C. 668–668d
Migratory Bird Treaty Act, 16 U.S.C. 703–712

Hazardous Materials Management

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601–9675
Superfund Amendments and Reauthorization Act (SARA), 42 U.S.C. 9671–9675
Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901–6992k

Historic and Cultural Resources

National Historic Preservation Act of 1966 (NHPA), as amended, 54 U.S.C. 300101–307108, *et seq.*, and implementing regulations at 23 CFR part 800, except to the extent 23 CFR 773.105(b)(4) requires FRA or FTA to retain responsibility for government-to-government consultation with Indian tribes
Archaeological Resources Protection Act of 1979 (ARPA), as amended, 16 U.S.C. 470aa–470mm
Preservation of Historical and Archeological Data, 54 U.S.C. 312501–312508

Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3001–3013; 18 U.S.C. 1170

Social and Economic Impacts

American Indian Religious Freedom Act, 42 U.S.C. 1996
Farmland Protection Policy Act (FPPA), 7 U.S.C. 4201–4209

Water Resources and Wetlands

Clean Water Act, 33 U.S.C. 1251–1387 (Sections 319, 401, 402, 404, and 408)
Emergency Wetlands Resources Act, 16 U.S.C. 3901 and 3921
Flood Disaster Protection Act, 42 U.S.C. 4001–4133
General Bridge Act of 1946, 33 U.S.C. 525–533
Rivers and Harbors Act of 1899, 33 U.S.C. 401–406
Safe Drinking Water Act (SDWA), 42 U.S.C. 300f–300j–26
Wetlands Mitigation, 23 U.S.C. 119(g) and 133(b)(3)
Wild and Scenic Rivers Act, 16 U.S.C. 1271–1287

Parklands and Other Special Land Uses

Section 4(f), 49 U.S.C. 303 and implementing regulations at 23 CFR part 774
Land and Water Conservation Fund (LWCF) Act, 54 U.S.C. 200302–200310

The proposed MOU would allow UDOT to act in the place of FRA and FTA in carrying out the environmental review-related functions described above, except with respect to Government-to-Government consultations with federally recognized Indian Tribes. UDOT would continue to handle routine consultations with the Tribes and understands that a Tribe has the right to direct consultation with FRA or FTA upon request. UDOT may assist FRA or FTA with Government-to-Government consultations, with consent of a Tribe, but FRA and FTA remain responsible for the consultation.

In addition, UDOT would not assume FRA's or FTA's responsibilities for conformity determinations required under 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.

FRA and FTA will consider the comments submitted on UDOT's joint application and the proposed MOU. A copy of the joint application package and proposed MOU may be viewed on the docket (FRA–2026–2740) at <https://www.regulations.gov>. A copy also may be viewed on UDOT's website at: <https://connect.udot.utah.gov/about-us/program-development-group/environmental-division/>. Any final

MOU approved by FRA and FTA may include changes based on comments and consultations relating to the proposed MOU and will be made publicly available.

(Authority: 23 U.S.C. 139; 23 U.S.C. 327; 42 U.S.C. 4331, 4332; 23 CFR part 771; 23 CFR part 773; 49 CFR 1.89; 49 CFR 1.91; 49 CFR part 264; and 49 CFR part 622.)

Marlys Ann Osterhues,

Director, Office of Environmental Program Management, Office of Railroad Administration, Federal Railroad Administration.

Megan Blum,

Deputy Associate Administrator, Office of Planning and Environment, Federal Transit Administration.

[FR Doc. 2026–21397 Filed 10–19–26; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2026–1981]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This document provides the public notice that the Indiana & Ohio Railway Company (IORY) petitioned FRA seeking approval to discontinue or modify a signal system.

DATES: FRA must receive comments on the petition by December 21, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the Privacy Act heading in the

SUPPLEMENTARY INFORMATION section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Scott Johnson, Railroad Safety Specialist, FRA Signal, Train Control, and Crossings Division, telephone: 406–210–3608, email: scott.j.johnson@dot.gov.

SUPPLEMENTARY INFORMATION: Under part 235 of title 49 Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that by letter dated July 20, 2026, IORY petitioned FRA seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2026–1981.

Specifically, IORY requests to discontinue the centralized traffic control (CTC) signal system in Cincinnati, Ohio. The subject area is on main tracks Nos. 1 and 2, between control point (CP) East Norwood (milepost (MP) 10.9) and CP NA Tower (MP 7.5) on the Midland Subdivision and between CP Oakley (MP 10.1) and CP Ridge (MP 10.6) on the Oasis Subdivision.

IOFY explains that the absolute signals and power-operated switches at CPs East Norwood, Bond Hill, Oakley, and Ridge would be removed. Further, all electric locks in the subject area will be removed, and the signal appliances will be removed from service. In its petition, IORY notes that the “current traffic density and operating characteristics of the territory no longer require” CTC for the safe movement of trains, as the line has no opposing train movements or fleeted operations. IORY adds that replacement parts for the obsolete CTC system are no longer manufactured, and repair options are limited. Finally, IORY states that the proposed operating method of converting the area to yard limit authority will “facilitate more efficient yard operations . . . and reduce the duration of occupancy at adjacent highway-rail grade crossings.”

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by December 21, 2026 will be considered

by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA’s dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. 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 <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2026–21388 Filed 10–19–26; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION**Federal Railroad Administration**

[Docket Number FRA–2026–2773]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This document provides the public notice that New Jersey Transit Rail Operations, Inc. (NJ Transit) petitioned FRA seeking approval to discontinue or modify a signal system.

DATES: FRA must receive comments on the petition by December 21, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to <https://www.regulations.gov> and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to <https://www.regulations.gov>; this includes any personal information. Please see the

Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Scott Johnson, Railroad Safety Specialist, FRA Signal, Train Control, and Crossings Division, telephone: 406–210–3608, email: scott.j.johnson@dot.gov.

SUPPLEMENTARY INFORMATION: Under part 235 of title 49 Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that by letter dated September 30, 2026, NJ Transit, along with Norfolk Southern Corporation (NS) and Morristown & Erie Railway, Inc. (M&E), petitioned FRA seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2026–2773.

Specifically, NJ Transit requests to retire the fixed automatic block signals on Tracks 1 and 2 on the Bergen County Line in Rutherford, New Jersey. The petition states that the existing signal system is a traffic control system, including automatic train control, cab signal, and positive train control systems, on the Hoboken Division between milepost (MP) 5.4 and controlled point West BJ MP 9.8.

In support of its request, NJ Transit states that removing the block signals will eliminate maintenance and operation of “unnecessary” hardware, reduce delays caused by potential signal failure, and lessen the frequency of employees climbing on signal bridges for maintenance. NJ Transit obtained and included concurrence on the permanent changes from representatives from NS and M&E.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by December 21, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. 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 <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

*Associate Administrator for Railroad Safety,
Chief Safety Officer.*

[FR Doc. 2026-21386 Filed 10-19-26; 8:45 am]

BILLING CODE 4910-06-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 October 13, 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 October 13, 2026, OFAC determined that one or more persons identified below meet one or more of the criteria for the imposition of sanctions set forth in section 1(a)-(c) of Executive Order 14059 of December 15, 2021, "Imposing Sanctions on Foreign Persons Involved in the Global Illicit Drug Trade," 86 FR 71549 (E.O. 14059). OFAC has selected to impose blocking sanctions pursuant to section 2(a)(i) of E.O. 14059 on the persons identified below.

OFAC further determined that one or more persons identified below meet one or more of the criteria for sanctions pursuant to Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism," 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, "Modernizing Sanctions To Combat Terrorism," 84 FR 48041 (collectively, "E.O. 13224, as amended").

As a result, the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. GUAJARDO ALVAREZ, Pablo Cesar (a.k.a. "El Takia"), Mexico; DOB 29 Dec 1998; POB Tamaulipas, Mexico; nationality Mexico; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; C.U.R.P. GUAP981229HTSJLB08 (Mexico) (individual) [SDGT] [ILLCIT-DRUGS-EO14059] (Linked To: CARTEL DEL NORESTE).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for having acted or purported to act for or on behalf of, directly or indirectly, Cartel del Noreste, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, Cartel del Noreste, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

2. GARZA GARCIA, Gamaliel, Anahuac, Nuevo Leon, Mexico; DOB 23

Oct 1974; POB Nuevo Leon, Mexico; nationality Mexico; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; C.U.R.P. GAGG741023HNLRRM06 (Mexico) (individual) [SDGT] [ILLCIT-DRUGS-EO14059] (Linked To: CARTEL DEL NORESTE).

Sanctioned pursuant to section 1(b)(i) of E.O. 14059 for having provided, or attempted to provide, financial, material, or technological support of, or goods or services in support of, Cartel del Noreste, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Cartel del Noreste, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

3. GARZA ELIAS, Gamaliel, Anahuac, Nuevo Leon, Mexico; DOB 10 Jul 1997; POB Nuevo Laredo, Tamaulipas, Mexico; nationality Mexico; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; C.U.R.P. GAEG970710HTSRLM04 (Mexico) (individual) [SDGT] [ILLCIT-DRUGS-EO14059] (Linked To: CONSTRUCCIONES Y EDIFICACIONES GARZA ELIAS, S.A. DE C.V.).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for having acted or purported to act for or on behalf of, directly or indirectly, Construcciones y Edificaciones Garza Elias, S.A. de C.V., a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for having acted or purported to act for or on behalf of, directly or indirectly, Construcciones y Edificaciones Garza Elias, S.A. de C.V., a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

4. INZUNZA PARTIDA, Francisco Javier (a.k.a. AMADOR INZUNZA, Francisco; a.k.a. "Pancho Amador"), Mexico; DOB 21 Nov 1986; POB Coahuila, Mexico; nationality Mexico; Gender Male; C.U.R.P. IUPF861121HCLNRR09 (Mexico) (individual) [ILLCIT-DRUGS-EO14059].

Sanctioned pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the

international proliferation of illicit drugs or their means of production.

Entities

1. CLUB LA MOLIENDA (a.k.a. LA MOLIENDA RACE TRACK; a.k.a. RESTAURANT BAR LA MOLIENDA), Nuevo Laredo, Tamaulipas, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Type: Operation of sports facilities; alt. Organization Type: Restaurants and mobile food service activities [SDGT] [ILLICIT-DRUGS-EO14059] (Linked To: CARTEL DEL NORESTE).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Cartel del Noreste, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Cartel del Noreste, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

2. CONSTRUCCIONES Y EDIFICACIONES GARZA ELIAS, S.A. DE C.V. (a.k.a. CEGESA; a.k.a. CEGESA S.A. DE C.V.), Anahuac, Nuevo Leon, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 09 Mar 2016; Organization Type: Construction of buildings; Folio Mercantil No. 5576 (Mexico) [SDGT] [ILLICIT-DRUGS-EO14059] (Linked To: GARZA GARCIA, Gamaliel).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

3. CUADRA SAN DIBANH, Anahuac, Nuevo Leon, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Type: Raising of horses and other equines [SDGT] [ILLICIT-DRUGS-EO14059]

(Linked To: GARZA GARCIA, Gamaliel).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

4. CONCRETOS Y PRODUCTOS ASFALTICOS DEL NORTE, S.A. DE C.V., Nuevo Laredo, Tamaulipas, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 20 Mar 2024; Organization Type: Construction of roads and railways; Folio Mercantil No. N-2024024028 (Mexico) [SDGT] [ILLICIT-DRUGS-EO14059] (Linked To: GARZA GARCIA, Gamaliel).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

5. CONSTRUACEROS DEL FUERTE, S.A. DE C.V., Nuevo Laredo, Tamaulipas, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 13 Mar 2024; Organization Type: Construction of buildings; Folio Mercantil No. N-2024028434 (Mexico) [SDGT] [ILLICIT-DRUGS-EO14059] (Linked To: GARZA GARCIA, Gamaliel).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act

for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

6. DISTRIBUIDORA DE GAS ECONOMICO, S.A. DE C.V., Nuevo Laredo, Tamaulipas, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 11 Mar 2025; Organization Type: Wholesale of solid, liquid and gaseous fuels and related products; Folio Mercantil No. N-2025031155 (Mexico) [SDGT] [ILLICIT-DRUGS-EO14059] (Linked To: GARZA GARCIA, Gamaliel).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

7. GAS ENERGIA CONFIABLE, S.A. DE C.V., Nuevo Laredo, Tamaulipas, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 11 Mar 2025; Organization Type: Wholesale of solid, liquid and gaseous fuels and related products; Folio Mercantil No. N-2025036516 (Mexico) [SDGT] [ILLICIT-DRUGS-EO14059] (Linked To: GARZA GARCIA, Gamaliel).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

8. INOVA NLD DESARROLLOS INMOBILIARIOS, S.A. DE C.V., Nuevo Laredo, Tamaulipas, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 05 Sep 2024; Organization Type:

Construction of buildings; Folio Mercantil No. N-2024082509 (Mexico) [SDGT] [ILLICIT-DRUGS-EO14059] (Linked To: GARZA GARCIA, Gamaliel).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

9. PROPANE TRADING GROUP, S.A. DE C.V., Nuevo Laredo, Tamaulipas, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 11 Mar 2025; Organization Type: Wholesale of solid, liquid and gaseous fuels and related products; Folio Mercantil No. N-2025031199 (Mexico) [SDGT] [ILLICIT-DRUGS-EO14059] (Linked To: GARZA GARCIA, Gamaliel).

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

10. TRANSPORTADORA DE GAS DE NUEVO LAREDO, S.A. DE C.V., Nuevo

Laredo, Tamaulipas, Mexico; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 11 Mar 2025; Organization Type: Wholesale of solid, liquid and gaseous fuels and related products; Folio Mercantil No. N-2025031250 (Mexico) [SDGT] [ILLICIT-DRUGS-EO14059].

Sanctioned pursuant to section 1(b)(iii) of E.O. 14059 for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a sanctioned person pursuant to E.O. 14059.

Designated pursuant to section 1(a)(iii)(A) of E.O. 13224, as amended, for being owned, controlled, or directed by, or having acted or purported to act for or on behalf of, directly or indirectly, Gamaliel Garza Garcia, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

11. TAMEX LOGISTICS (a.k.a. TAMEX LEASING), Villa de Hidalgo 239, Granjas Guzman, Nuevo Laredo, Tamaulipas 88293, Mexico; Organization Type: Transportation and storage; Standard Carrier Alpha Code (SCAC) TLOJ;Codigo Alfanumerico Armonizado del Transportista (CAAT) 7547 (Mexico) [ILLICIT-DRUGS-EO14059].

Sanctioned pursuant to section 1(a)(i) of E.O. 14059 for having engaged in, or attempted to engage in, activities or transactions that have materially contributed to, or pose a significant risk of materially contributing to, the international proliferation of illicit drugs or their means of production.

(Authority: E.O. 14059; E.O. 13224, as amended.)

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2026-21445 Filed 10-19-26; 8:45 am]

BILLING CODE 4810-AL-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 October 15, 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 October 15, 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. MIRMOHAMMADI, Mansureh (Arabic: منصوره ميرمحمدی), Iran; DOB 13 May 1982; POB Golpayegan, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; National ID No. 1219437239 (Iran) (individual) [IRAN-EO13902] (Linked To: SOHEIL AND SORUSH NAJAFZADEH AND PARTNERS COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 of September 28, 2010, "Imposing Sanctions With Respect to Additional Sectors of Iran," 85 FR 2003, 3 CFR, 2020 Comp., p. 299 (E.O. 13902), for having acted or purported to act for or on behalf of, directly or indirectly, SOHEIL AND SORUSH NAJAFZADEH AND PARTNERS COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

2. NAJAFZADEH, Soroush (Arabic: سروش نجف زاده) (a.k.a. NAJAFZADEH, Sorosh), Iran; DOB 27 Aug 1982; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0069940177 (Iran) (individual) [IRAN-EO13902].

Designated pursuant to sections 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

3. NAJAFZADEH, Soheil (Arabic: سهیل نجف زاده) (a.k.a. NAJAFZADEH, Suhail), Iran; DOB 12 Apr 1976; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0069004250 (Iran) (individual) [IRAN-EO13902].

Designated pursuant to sections 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

4. RAZAVI, Sayyed Ruhollah (Arabic: سید روح اله رضوی) (a.k.a. RAZAVI, Rouhollah; a.k.a. RAZAVI, Ruhollah; a.k.a. ROOHULLAH RAZAVI, Seyed), Iran; Dubai, United Arab Emirates; DOB 19 Sep 1981; POB Qom, Iran; nationality Iran; citizen Dominica; alt. citizen Turkey; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0381818969 (Iran) (individual) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the petroleum sector of the Iranian economy.

5. ABDOLALIPUR, Azadeh (Arabic: آزاده عبدالعلی پور) (a.k.a. ALIPUR, Azadeh), Iran; DOB 11 Sep 1988; POB Shiraz, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; National ID No. 2300151421 (Iran) (individual) [IRAN-EO13902] (Linked To: FARAB SOROUGH AFAGH QESHM COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, FARAB SOROUGH AFAGH QESHM COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

6. ALLAHYAR, Farzad (Arabic: فرزاد الهيار), Iran; DOB 12 Aug 2001; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0024557455 (Iran) (individual) [IRAN-EO13902] (Linked To: FARAB SOROUGH AFAGH QESHM COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, FARAB SOROUGH AFAGH QESHM COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

7. BORJI, Nazanin (Arabic: نازنین برجی), Iran; DOB 10 Jun 1996; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; National ID No. 0019123337 (Iran) (individual) [IRAN-EO13902] (Linked To: FARAB SOROUGH AFAGH QESHM COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, FARAB SOROUGH AFAGH QESHM COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

8. KATEBI, Milad (Arabic: میلاد کاتبی), Iran; DOB 31 Dec 1989; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0011436913 (Iran) (individual) [IRAN-EO13902] (Linked To: FARAB SOROUGH AFAGH QESHM COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, FARAB SOROUGH AFAGH QESHM COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

9. MOHAMMADI, Zhila (Arabic: ژيلا محمدی) (a.k.a. MOHAMADI, Jela; a.k.a. MOHAMMADI ALIABAD, Zhila (Arabic: ژيلا محمدی علی آباد)), Iran; DOB 28 Jun 1991; POB Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; National ID No. 5660004288 (Iran) (individual) [IRAN-EO13902] (Linked To: FARAB SOROUGH AFAGH QESHM COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, FARAB SOROUGH

AFAGH QESHM COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

10. SABETI, Amir (Arabic: امير ثابتي), Iran; DOB 30 Aug 1981; POB Shemiran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0451397711 (Iran) (individual) [IRAN-EO13902] (Linked To: FARAB SOROUSH AFAGH QESHM COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, FARAB SOROUSH AFAGH QESHM COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

11. VASIGHI MERAJI, Fatemeh (Arabic: فاطمه وثيقي معراجي) (a.k.a. VASIGHI, Fatemeh), Iran; DOB 21 Aug 1987; POB Qom, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; National ID No. 0386128804 (Iran) (individual) [IRAN-EO13902] (Linked To: FARAB SOROUSH AFAGH QESHM COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, FARAB SOROUSH AFAGH QESHM COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

12. JALALI, Abolhasan (Arabic: ابوالحسن جلالی), Iran; DOB 01 Sep 1966; POB Maragheh, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 1550929674 (Iran) (individual) [IRAN-EO13902].

Designated pursuant to sections 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

13. MULLAH MOHAMMADI, Ensiyeh (Arabic: انسيه ملامحمدي), Iran; DOB 18 May 1976; POB Qom, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Female; National ID No. 0381750760 (Iran) (individual) [IRAN-EO13902].

Designated pursuant to sections 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

14. BAVI, Sadeq (Arabic: صادق باوی), Dubai, United Arab Emirates; DOB 21 Mar 1964; POB Ahvaz, Iran; nationality Iran; alt. nationality Dominica; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport N97128850 (Iran) expires 11 May 2027; alt. Passport RA045652 (Dominica) expires 26 Sep 2032 (individual) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in financial sector of the Iranian economy.

15. HOSSEINI PARSA, Seyyed Abbas (Arabic: سيد عباس حسيني پارسا), Iran; DOB 15 Jul 1956; POB Tehran, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 0083131019 (Iran) (individual) [IRAN-EO13902] (Linked To: SEYYED ABBAS HOSSEINI PARSA AND PARTNERS QESHM GENERAL PARTNERSHIP COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, SEYYED ABBAS HOSSEINI PARSA AND PARTNERS QESHM GENERAL PARTNERSHIP COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

16. MOHIESNEJAD, Khaled (Arabic: خالد محسن نژاد), Iran; DOB 21 Sep 1982; POB Ahvaz, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 1754430317 (Iran) (individual) [IRAN-EO13902] (Linked To: SEYYED ABBAS HOSSEINI PARSA AND PARTNERS QESHM GENERAL PARTNERSHIP COMPANY).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for having acted or purported to act for or on behalf of, directly or indirectly, SEYYED ABBAS HOSSEINI PARSA AND PARTNERS QESHM GENERAL PARTNERSHIP COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902.

Entities

1. CHABAHAR INTERNATIONAL BANK OVERSEAS COMPANY (Arabic: شرکت بانک بین المللی چابهار برون مرزی), Unit 173, Second Floor, Booth 303, Salehyar Complex, No. 0, Vahdat Street, Imam Khomeini Boulevard, Free Zone Neighborhood, Central District, Chabahar Country, Chabahar City, Sistan and Baluchestan Province 9971768361, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 17 Jan 2022; Target Type Financial Institution; National ID No. 14010705831 (Iran); Registration Number 4060 (Iran) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

2. SOHEIL AND SORUSH NAJAFZADEH AND PARTNERS COMPANY (Arabic: شرکت سهیل و سروش نجف زاده و شرکا), Ground Floor, No. 149, Sarv Sharghi Boulevard, Majd Street, Saadat Abad, Tehran, Central District, Tehran 1998644341, Iran; Additional Sanctions Information - Subject to Secondary

Sanctions; Organization Established Date 07 Apr 2015; Organization Type: Other monetary intermediation; National ID No. 14004832696 (Iran); Registration Number 470601 (Iran) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

3. FARZANEGAN ENERGY PARS COMPANY

(Arabic: شرکت فرزندگان انرژی پارس), North Unit, First Floor, No. 14, Shahid Davoud Jahanbaksh Nejad Street, Farmanieh, Tajrish, Tehran 1957944813, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 26 Oct 2015; National ID No. 14005314445 (Iran) [IRAN-EO13902] (Linked To: RAZAVI, Sayyed Ruhollah).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, SAYYED RUHOLLAH RAZAVI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

4. TEJARAT GOSTAR ATLAS PARSIAN KISH COMPANY

(Arabic: شرکت تجارت گستر اطلس پارسیان کیش), Unit 208, Second Floor, Plot EX20, Sepehr Building, Eghtesad Square, Iran Boulevard, Kish Industrial Phase 2, Kish, Hormozgan 7941658112, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 24 Feb 2015; National ID No. 14004757110 (Iran) [IRAN-EO13902] (Linked To: RAZAVI, Sayyed Ruhollah).

Designated pursuant to section 1(a)(iv) of E.O. 13902 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, SAYYED RUHOLLAH RAZAVI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

5. JAZIREH INTERNATIONAL BANK COMPANY (Arabic: بانک بین المللی جزیره) (a.k.a. BANK-E BEINAMELALI JAZIREH), Ground Floor, NBO-9, No. 0, Andisheh Boulevard, Sanai Boulevard, Bank Complex, Kish District, Bandar-e Lengeh County, Kish, Hormozgan 7941773662, Iran; Kish, Hormozgan, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 03 Jan 2022; Target Type Financial Institution; National ID No. 14010665053 (Iran); Registration Number 14485 (Iran) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

6. INTERNATIONAL DEVELOPMENT BANK FOR INVESTMENT AND FINANCE (Arabic: مصرف التنمية الدولي للاستثمار والتمويل) (a.k.a. IRAQ

DEVELOPMENT BANK; a.k.a. "INTERNATIONAL DEVELOPMENT BANK"), Arasat Ave, Karada, Baghdad, Iraq; Karrada, Hay Babil Dist. 929, Arasat Ave., St No. 21, Building 1, Baghdad 10069, Iraq; SWIFT/BIC IDBQIQBA; Website <https://www.idb.iq>; Organization Established Date 11 Jan 2011; Target Type Financial Institution; Legal Entity Number 2549001T72VRU0W37E62 [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

7. ABOLHASAN JALALI AND PARTNERS EXCHANGE COMPANY (Arabic: شرکت صرافی ابوالحسن جلالی و شرکا) (a.k.a. JALALI AND PARTNERS GENERAL PARTNERSHIP COMPANY), Ground Floor, Salarieh Commercial Complex, No. 0, Mohammad Amin Boulevard, Iran Marinos Street, Salarieh, Qom, Central District, Qom Province 3716975454, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 04 May 2016; Organization Type: Other monetary intermediation; National ID No. 14005814280 (Iran); Registration Number 14150 (Iran) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

8. ELITESPHERE TRADING CO., LIMITED, Rm 9042, 9/F, Block B, Chung Mei Centre, 15-17 Hong Yip Street, Kwun Tong, Hong Kong, China; Unit 11, 9/F, The Cloud, No. 111 Tuang Chau Street, Tai Koktsui, Kowloon, Hong Kong, China; Organization Established Date 20 Aug 2024; Business Registration Number 76961842 (Hong Kong) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

9. BAVI AND PARTNERS EXCHANGE COMPANY (Arabic: شرکت صرافی باوی و شرکاء), Unit 3, Floor 2, No. 114, Karim Khan Zand Boulevard, Mahshahr Street, Iranshahr, Tehran 1584773815, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 18 Nov 2024; Organization Type: Other monetary intermediation; National ID No. 14013961908 (Iran); Registration Number 641804 (Iran) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

10. SEYYED ABBAS HOSSEINI PARSA AND PARTNERS QESHM GENERAL PARTNERSHIP COMPANY (Arabic: شرکت تضامنی سید عباس حسینی پارسا و شرکا قشم), Unit 2078, Ground Floor, Atta, Ferdowsi Qeshm Commercial Complex Passage, No. 0, Vali Asr Boulevard,

Main Street, Sina Desert, Central District, Qeshm, Hormozgan 7951919639, Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Organization Established Date 14 Jun 2016; Organization Type: Other monetary intermediation; National ID No. 14005927381 (Iran); Registration Number 5549 (Iran) [IRAN-EO13902].

Designated pursuant to section 1(a)(i) of E.O. 13902 for operating in the financial sector of the Iranian economy.

(Authority: E.O. 13902.)

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2026-21398 Filed 10-19-26; 8:45 am]

BILLING CODE 4810-AL-C

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons whose property and interests in property have been unblocked and who have been removed from the SDN List.

DATES: 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

A. On September 3, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person is unblocked and they have been removed from the SDN List.

1. DULAC CAPITAL LTD (a.k.a. AK DYULAK KEPITAL LTD PREDSTAVITELSTVO; a.k.a. PREDSTAVITELSTVO AKTSIONERNOGO OBSHCHESTVA DYULAK KEPITAL LTD SHVEITSARIYA V G MOSCOW; a.k.a. PREDSTAVITELSTVO AKTSIONERNOGO OBSHCHESTVA DYULAK KEPITAL LTD SHVEITSARIYA V G SANKT PETERBURGE), Arosastrasse 7, Zurich 8008, Switzerland; Pr-kt Morskoi pom. 12-N, Saint Petersburg 197110, Russia; Pr-kt Leningradskii, Moscow 125167, Russia; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 14 Dec 2007; Tax ID No. 113974567 (Switzerland); alt. Tax ID No. 9909354395 (Russia); Identification Number SRWNNB.99999.SL.756 (Switzerland); Legal Entity Number 529900E3569EJW938341; Registration Number CH-020.3.031.775-0 (Switzerland) [RUSSIA-EO14024].

B. On September 16, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are unblocked and they have been removed from the SDN List.

1. BOMATTER, Hans Peter, La Zubia, Spain; DOB 19 May 1965; POB

Schattdorf, Switzerland; nationality Switzerland; Gender Male; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Passport F3848406 (Switzerland) (individual) [RUSSIA-EO14024] (Linked To: TAMYNA AG).

2. VEGA SANCHEZ, Jose Raul, c/o AGRICOLA GAXIOLA S.A. DE C.V., Hermosillo, Sonora, Mexico; c/o INMUEBLES SIERRA VISTA S.A. DE C.V., Hermosillo, Sonora, Mexico; c/o TEMPLE DEL PITIC S.A. DE C.V., Hermosillo, Sonora, Mexico; DOB 19 Oct 1956; POB Cananea, Sonora, Mexico; nationality Mexico; citizen Mexico; C.U.R.P. VESR561019HSRGNL09 (Mexico); alt. C.U.R.P. VEXR561019HSRGXL05 (Mexico) (individual) [SDNTK].

3. MODULSAN MAKINA KESICI TAKIM VE DISLI SANAYI TICARET LIMITED SIRKETI, 1CA Blok, 1575. Sokak No. 1 CA/2, Akcaburgaz Mahallesi, Esenyurt 34522, Turkey; website www.modulsan.com; Secondary sanctions risk: See Section 11 of Executive Order 14024.; Organization Established Date 09 Oct 2006; Tax ID No. 3340494281 (Turkey); Identification Number 0334049428100019 (Turkey); Registration Number 602993 (Turkey) [RUSSIA-EO14024].

C. On September 17, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are unblocked and they have been removed from the SDN List.

1. BELARUSIAN PRODUCTION AND TRADE CONCERN OF TIMBER WOODWORKING AND PULP AND PAPER INDUSTRY (Cyrillic: БЕЛОРУССКИЙ ПРОИЗВОДСТВЕННО ТОРГОВЫЙ КОНЦЕРН ЛЕСНОЙ ДЕРЕВООБРАБАТЫВАЮЩЕЙ И ЦЕЛЛЮЛОЗНО БУМАЖНОЙ ПРОМЫШЛЕННОСТИ) (a.k.a. BIELARUSKI VYTVORCHA HANDLIOVY KANCERN LIASNOJ DREVAAPRACOWCHAJ I CELIULOZNA PARIAROVAJ PRAMYSLOVACSI (Cyrillic: БЕЛАРУСКИ ВЫТВОРЧА ГАНДЛЁВЫ КАНЦЭРН ЛЯСНОЙ ДРЭВААПРАЦОЎЧАЙ І ЦЭЛЮЛОЗНА ПАПЯРОВАЙ ПРАМЫСЛОВАСЦІ); a.k.a. KONTSERN BELLESBUMPROM (Cyrillic: КОНЦЕРН БЕЛЛЕСБУМПРОМ)), GSP, K. Marx Street, 16, Minsk 220030, Belarus; Organization Established Date 21 Jun 1991; Target Type State-Owned Enterprise; Tax ID No. 100377850 (Belarus) [BELARUS-EO14038].

2. LAKOKRASKA OAO (a.k.a. LAKOKRASKA OPEN JOINT-STOCK COMPANY), 71 Ignatova Street, Grodnenskaya Region, Lida 231300, Belarus; ul. Ignatova, 71, Grodnenskaya oblast, Lida 231300, Belarus [BELARUS].

D. On September 23, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are unblocked and they have been removed from the SDN List.

1. OLENGA, Francois (Latin: OLENGA, François) (a.k.a. OKUNJI, Francois (Latin: OKUNJI, François); a.k.a. OLENGA TATE, Francois; a.k.a. OLENGA TETE, Francois (Latin: OLENGA TETE, François); a.k.a. OTSHUNDI, Francois (Latin: OTSHUNDI, François)), Kinshasa, Congo, Democratic Republic of the; DOB 09 Oct 1948; alt. DOB 10 Sep 1948; alt. DOB 10 Jul 1949; POB Kindu, Maniema, Democratic Republic of the Congo; nationality Congo, Democratic Republic of the; citizen Congo, Democratic Republic of the; Gender Male; General; Chef de la Maison Militaire; Head of the Military House of the President (individual) [DRCONGO].

2. SAFARI CLUB (a.k.a. CENTRE DE LOISIR SAFARI CLUB; a.k.a. "SAFARI BEACH"), Nsele, Kinshasa, Congo, Democratic Republic of the; Gombe, Kinshasa, Congo, Democratic Republic of the; Registration ID 1322 (Congo, Democratic Republic of the) [DRCONGO] (Linked To: OLENGA, Francois).

E. On September 30, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are unblocked and they have been removed from the SDN List.

1. PROTOPOVICH, Tatyana (a.k.a. PROTOPOVICH, Tayuana), Praspiekt Dziarzynsakaha, 82, Flat 227, Minsk

22089, Belarus; DOB 24 Mar 1996; nationality Belarus; Gender Female; Passport MP4133985 (Belarus); National ID No. 4240396A013PB6 (Belarus) (individual) [BELARUS-EO14038] (Linked To: CENTURONIC LTD).

2. PATRACA, S.A. DE C.V. (a.k.a. BOUTIQUE PATRACA), Calle Miguel Hgo No. 302, Col. Centro, Culiacan, Sinaloa, Mexico; Ave. Alvaro Obregon No. 1800, 74M, Col. Colinas de San Miguel, Culiacan, Sinaloa 80228, Mexico; Col. Proyecto Urbano Tres Rios, Culiacan, Sinaloa, Mexico; Calle Benito Juarez, No. 302, Col. Centro, Culiacan, Sinaloa, Mexico; Calle Benito Juarez 302 A altos S/N, Col. Centro, Culiacan, Sinaloa, Mexico; Alvaro Obregon y Cerro de Montelargo Local 74M, 75M, 76M, 7 Colinas de San Miguel, Culiacan 80228, Mexico; Ave Alvaro Obregon No. 1800, 74M, Col. Colinas de San Miguel, Culiacan, Sinaloa 80228, Mexico; Cll Jose Diego Valadez Rios 16, Plaza Patraca PB-24, Proyecto Urbano Tres Rios, Culiacan Rosales, Culiacan 80000, Mexico; Cll Jose Diego Valadez Rios 16, Plaza Patraca PB-16, Proyecto Urbano Tres Rios, Culiacan Rosales, Culiacan 80000, Mexico; Cll Jose Diego Valadez Rios 16, Plaza Patraca PB-39, Proyecto Urbano Tres Rios, Culiacan Rosales, Culiacan 80000, Mexico; Cll Jose Diego Valadez Rios No. 1676, Col. Proyecto Urbano Tres Rios, Culiacan, Sinaloa 80000, Mexico; R.F.C. PAT040318GF7 (Mexico) [SDNTK].

F. On September 30, 2026, OFAC determined that the following vessel is unblocked and has been removed from the SDN List.

1. MARAYA (f.k.a. MED PATRON) Palletized Cargo Ship Samoa flag; Vessel

Registration Identification IMO 7514517 (vessel) [LIBYA3] (Linked To: ALWEFAQ LTD).

G. On October 8, 2026, OFAC determined that the following vessels are unblocked and have been removed from the SDN List.

1. HAKUNA MATATA (5LBT7) Container Ship Liberia flag; Vessel Year of Build 2008; Vessel Registration Identification IMO 9354167; MMSI 636021002 (vessel) [IRAN-EO13902] (Linked To: MARVISE SMC DMCC).

2. PINOCCHIO (5LAB8) Container Ship Liberia flag; Vessel Year of Build 2009; Vessel Registration Identification IMO 9400112; MMSI 636020659 (vessel) [IRAN-EO13902] (Linked To: MARVISE SMC DMCC).

(Authority: 31 CFR chapter V.)

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2026-21423 Filed 10-19-26; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; New Markets Tax Credit Program (NMTC Program) Allocation and Qualified Equity Investment Tracking System (AQEI)

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 19, 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:

Community Development Financial Institutions Fund (CDFI)

1. *Title:* New Markets Tax Credit Program (NMTCP Program) Allocation and Qualified Equity Investment Tracking System (AQEI).

OMB Control Number: 1559-0024.

Type of Request: Extension without change of a currently approved collection.

Description: The Allocation Agreement contains the terms and conditions, including all reporting requirements, associated with the receipt of an NMTCP Program allocation. The CDFI Fund requires each Allocatee to use an electronic data collection and submission system, known as the Allocation and Qualified Equity Investment Tracking System (AQEI), to report on the information related to its receipt of a Qualified Equity Investment.

Form: None.

Affected Public: Not-for-profit institutions, businesses or other for-profit institutions and State, Local and Tribal Government.

Estimated Number of Respondents: 202.

Frequency of Response: On occasion.
Estimated Total Number of Annual Responses: 1,010.

Estimated Time per Response: 1.7 hours.

Estimated Total Annual Burden Hours: 1,717.

(Authority: 44 U.S.C. 3501 *et seq.*)

Juliana L. Pearson,

Treasury PRA Clearance Officer.

[FR Doc. 2026-21455 Filed 10-19-26; 8:45 am]

BILLING CODE 4810-70-P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for Extension of Time To Furnish Recipient Statements

AGENCY: Internal Revenue Service (IRS), 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 19, 2026 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Copies of the submissions may be obtained from Spencer W. Clark by emailing PRA@treasury.gov, calling (202) 927-5331, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

Title: Application for Extension of Time to Furnish Recipient Statements.
OMB Control Number: 1545-2313.

Type of Request: Extension without change of a currently approved collection.

Description: The Secretary may grant an extension of time in which to furnish to employees/contractors the statements required by law. Currently, regulations allow the taxpayer to request an extension of time via letter. This form provides taxpayers with a more structured way of making the request. This will ease the burden on the taxpayers and improve IRS processing time.

Form: 15397.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 35,000.

Frequency of Response: Annually.
Estimated Total Number of Annual Responses: 35,000.

Estimated Time per Response: 0.72 hours.

Estimated Total Annual Burden Hours: 25,200.

Authority: 44 U.S.C. 3501 *et seq.*

Juliana L. Pearson,

Treasury PRA Clearance Officer.

[FR Doc. 2026-21400 Filed 10-19-26; 8:45 am]

BILLING CODE 4831-GV-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0936]

Agency Information Collection Activity: VA Pilot Program on Graduate Medical Education and Residency (PPGMER)

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration (VHA), 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 a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Comments must be received on or before December 21, 2026.

ADDRESSES: Comments must be submitted through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Program-specific information: Rebecca Minnall, 202-695-9434, vhacopra@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, VHA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the

information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: VA Pilot Program on Graduate Medical Education and Residency (PGMER).

OMB Control Number: 2900–0936. <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: Extension without change of a currently approved collection.

Abstract: Section 403 of the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018 (Public Law 115–182; as codified at 38 U.S.C. 7302) mandated that VA create a pilot program to establish additional graduate medical education (GME) physician residency placement positions at certain covered facilities. The pilot program has been implemented and places no fewer than 100 resident physicians at covered facilities (sites) operated by Indian tribe or tribal organization (25 U.S.C. 5304), Indian Health Service, Federally-Qualified Health Centers (42 U.S.C. 1396d(1)(2)(B)) and Department of Defense. Participants in this program are required by the statute to collect and provide VA with programmatic data. VA is required to include this information in an annual Congressionally Mandated Report until the program terminates on August 7, 2031. The information will continue to be collected by the GME sponsoring institutions and the physician residents they place in the participating covered facilities. The sponsors themselves will determine the best method for collecting the necessary data, depending on their own resources and staffing. The information collected includes required elements, such as number of patients seen per day by each resident placed in a covered facility, and consolidated data from the GME sponsoring institutions. VA will submit this information in an annual report to Congress on continued implementation of the pilot program.

Total Annual Number of Respondents: 110.

Total Annual Time Burden: 1,800 hours.

Physician Resident Data Collection

Affected Public: Individuals or Households.

Estimated Annual Burden: 600 hours.

Estimated Average Burden Per Respondent: 6 hours.

Frequency of Response: Once annually.

Estimated Number of Respondents: 100.

GME Sponsor Data Collection

Affected Public: Private Sector.

Estimated Annual Burden: 1,200 hours.

Estimated Average Burden Per Respondent: 120 hours.

Frequency of Response: Once annually.

Estimated Number of Respondents: 10.

(Authority: 44 U.S.C. 3501 *et seq.*)

Lanea Haynes,

Alternate, VA PRA Clearance Officer, Office of Information and Technology, Office of Data Governance and Analytics, Department of Veterans Affairs.

[FR Doc. 2026–21411 Filed 10–19–26; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0661]

Agency Information Collection

Activity: State Veterans Homes Construction & Acquisition Grant Program (SVHCGP)

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration (VHA), 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 a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. DATES: Comments must be received on or before December 21, 2026.

ADDRESSES: Comments must be submitted through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Program-specific information: Rebecca Mimmall, 202–695–9434, vhacopra@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, VHA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA'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: State Veterans Homes Construction & Acquisition Grant Program (SVHCGP), VA Forms 10–0388–1, 10–0388–2, 10–0388–3, 10–0388–4, 10–0388–5, 10–0388–6, 10–0388–7, 10–0388–8, 10–0388–9, 10–0388–10, 10–0388–12, 10–0388–13.

OMB Control Number: 2900–0661. <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: This collection of information is authorized under 38 U.S.C. 8133(a) and 8135(a), which appropriate the expenditure of funds for State Home Domiciliary, Nursing Home, and Hospital Care. These sections of the U.S.C. require, among other things, that the State government or recognized Federal tribe (government) applicant provide the Department of Veterans Affairs (VA) with an application package. Only State governments and Federally recognized tribes (their governments) may submit the information to complete an application for the State Veterans Homes Construction & Acquisition Grant Program (SVHCGP); private groups or citizens are not eligible.

Applicants will complete VA Forms 10–0388–1, 10–0388–2, 10–0388–3, 10–

0388-4, 10-0388-5, 10-0388-6, 10-0388-7, 10-0388-8, 10-0388-9, 10-0388-10, 10-0388-12, and 10-0388-13 to apply for the SVHCGP and certify compliance with VA requirements. VA will use this information, along with other documents submitted by the State and Federally recognized tribe applicants, to evaluate the feasibility of the projects for VA participation and determine eligibility for grant awards. There is a decrease in the estimated number of annual responses and burden hours based upon program data since the last PRA clearance and the projected number of annual applicants.

Affected Public: State, Local, or Tribal Governments.

Estimated Annual Burden: 720 hours.

Estimated Average Burden per Respondent: 24 hours.

Frequency of Response: Once.

Estimated Number of Responses: 30.

Authority: 44 U.S.C. 3501 *et seq.*

Lanea Haynes,

Alternate, VA PRA Clearance Officer, Office of Information and Technology, Office of Data Governance and Analytics, Department of Veterans Affairs.

[FR Doc. 2026-21468 Filed 10-19-26; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0110]

Agency Information Collection Activity: Application for Assumption Approval and/or Release From Personal Liability to the Government on a Home Loan

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments and recommendations for the proposed information collection should be sent by November 19, 2026.

ADDRESSES: To submit comments and recommendations for the proposed information collection, please type the following link into your browser: www.reginfo.gov/public/do/PRAMain, select “Currently under Review—Open for Public Comments”, then search the list for the information collection by Title or “OMB Control No. 2900-0110.”

FOR FURTHER INFORMATION CONTACT:

VA PRA information: Dorothy Glasgow, 202-461-1084, VAPRA@va.gov.

SUPPLEMENTARY INFORMATION:

Title: Application for Assumption Approval and/or Release from Personal Liability to the Government on a Home Loan.

OMB Control Number: 2900-0110
<https://www.reginfo.gov/public/do/PRAsearch>.

Type of Review: Revision of a Currently Approved Collection.

Abstract: VA Form 26-6381, Application for Assumption Approval and/or Release from Personal Liability to the Government on a Home Loan is

completed by Veterans who are selling their homes by assumption rather than requiring purchasers to obtain their own financing to pay off the loan. The data furnished on the form is essential to determinations for assumption approval, release of liability, and substitution of entitlement in accordance with 38 U.S.C. 3713(a) and 3714 and 3702(b)(2). The respondent count increased from 1,000 to 5,000, which also increased the annual burden hours from 167 hours to 835 hours. This was due to the increasing number of assumptions due to the availability of assumable low-interest rate loans in the currently high-interest rate environment.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at insert citation date 91 FR 52403, August 13, 2026

Affected Public: Individuals or Households.

Estimated Annual Burden: 835 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: One-Time.

Estimated Number of Respondents: 5,000 per annual.

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. 2026-21454 Filed 10-19-26; 8:45 am]

BILLING CODE 8320-01-P



FEDERAL REGISTER

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October 20, 2026

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

Medicare Program; Implementation of Sections 6219, 6220, and 6224 of the Consolidated Appropriations Act, 2026; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS-4214-P]

RIN 0938-AV88

Medicare Program; Implementation of Sections 6219, 6220, and 6224 of the Consolidated Appropriations Act, 2026

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement section 6219 (Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals), section 6220 (Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act), and section 6224 (Modernizing and Ensuring Pharmacy Benefit Manager Accountability) of the Consolidated Appropriations Act, 2026.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time on December 15, 2026.

ADDRESSES: In commenting, please refer to file code CMS-4214-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov/docket/CMS-2026-2533>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4214-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4214-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Kristy Nishimoto, (206) 615-2367—General Questions and section 6219 of the Consolidated Appropriations Act, 2026.

James Clark, (410) 786-3875—Section 6220 of the Consolidated Appropriations Act, 2026. *PartDPBM@cms.hhs.gov*—Section 6224 of the Consolidated Appropriations Act, 2026.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at <https://www.regulations.gov/>.

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C) program and the Medicare Prescription Drug Benefit (Part D) program to implement section 6219 (Adjustments to Medicare Part D Cost-Sharing Reductions For Low-Income Individuals), section 6220 (Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act), and section 6224 (Modernizing and Ensuring Pharmacy Benefit Manager Accountability) of the Consolidated Appropriations Act, 2026 (CAA).

We note that, as with previous rules, any new marketing and communications policies in this rule are proposed to be applicable for all contract year 2028 marketing and communications, beginning October 1, 2027.

B. Summary of the Key Provisions

1. Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals (Section 6219 of the Consolidated Appropriations Act, 2026)

CMS is proposing to implement section 6219 of the CAA that would reduce the generic drug copayment from \$1 to \$0 for full-benefit dual eligible individuals at or below 100 percent of the Federal Poverty Level, effective for plan years starting January 1, 2028.

2. REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026)

CMS proposes to codify regulations to implement section 6220 of the CAA, titled the Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act, which establishes new provider directory accuracy and accountability requirements for Medicare Advantage (MA) organizations beginning in contract year 2028. Specifically, CMS proposes requirements to implement this new law related to provider directory verification and maintenance standards, annual accuracy analysis and reporting, public reporting of accuracy scores, and cost sharing protections for enrollees who rely on inaccurate provider directory information. CMS also proposes to codify the statutory requirements for contract year 2029, including that CMS must publicly display provider directory accuracy scores in a machine-readable format and MA organizations must prominently display those scores in their provider directories. Through these proposed codifications implementing the REAL Health Providers Act, CMS seeks to promote provider directory accuracy and accountability among MA organizations to ensure that beneficiaries are provided with clear, accurate information on the network of providers available to meet their health care needs.

3. Modernizing and Ensuring Pharmacy Benefit Manager Accountability (Section 6224 of the Consolidated Appropriations Act, 2026)

CMS has several proposals to implement section 6224 of the CAA, which established requirements related to pharmacy benefit managers (PBMs) and their affiliates specific to the Medicare Part D program. These proposals include new and enhanced requirements governing the remuneration that PBMs and their affiliates may receive for services in connection with the utilization of Part D drugs, data reporting by PBMs to Part D plan sponsors and CMS, transparency in

price guarantee arrangements between PBMs or their affiliates and Part D plan sponsors, disclosure by PBMs to Part D plan sponsors of the terms of certain agreements between PBMs or their

affiliates and pharmaceutical manufacturers, and other requirements added by the CAA. CMS also proposes to define key terms related to such requirements and establish compliance

and enforcement mechanisms, including disgorgement of funds to CMS for violations of the remuneration requirements.

C. Summary of Costs and Benefits

TABLE I.1: SUMMARY OF PROVISIONS AND FINANCIAL IMPACTS

Provision	Description	Financial Impact
Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals (Section 6219 of the Consolidated Appropriations Act, 2026)	This proposal would implement section 6219 of the CAA that would reduce the generic drug copayment from \$1 to \$0 for full-benefit dual eligible individuals.	The elimination of the copayment on non-multi-source generic drugs is a transfer, not a cost of the proposed provision. Beneficiaries who previously paid the copay will no longer bear that cost; the Medicare program will absorb it instead.
REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026)	This proposal would codify regulations to implement the REAL Health Providers Act, which establishes new provider directory accuracy and accountability requirements for MA organizations beginning in contract year 2028.	The proposal is expected to increase administrative and compliance costs for MA organizations associated with provider directory verification, accuracy reporting, processing requests for cost sharing protections, and related data infrastructure investments.
PBM Compensation and Transparency	This proposal would implement Section 6224 of the Consolidated Appropriations Act, 2026, establishing new and enhanced requirements governing PBM remuneration, data reporting, pricing transparency, and disclosure of manufacturer agreements within Medicare Part D, along with definitions of key terms and compliance and enforcement mechanisms, including disgorgement of funds to CMS for violations.	The financial impact of this proposal is not able to be estimated due to the lack of data on PBM contract structures and the difference between current fee levels and the proposed fair market value.

D. Conclusion

Finally, we are clarifying and emphasizing our intent that if any provision of this rule, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we propose provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements).

II. Implementation of Certain Provisions of the Consolidated Appropriations Act, 2026

A. Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals (Section 6219 of the Consolidated Appropriations Act, 2026) (§ 423.782)

In the Medicare Program, Medicare Prescription Drug Benefit Final Rule (70 FR 4194), CMS codified at § 423.782(a)(2)(iii)(A) and (B) the cost-sharing requirements for full-benefit dual eligible (FBDE) individuals with incomes that do not exceed 100 percent of the Federal Poverty Level (FPL) pursuant to section 1860D–14(a) of the

Act, codified at 42 U.S.C. 1395w–114(a). Under these provisions, individuals are subject to cost-sharing for covered Part D drugs equal to the lesser of the following:

- A copayment amount of no more than \$1 for a generic drug, approved biological product, or preferred drugs that are multiple source, or \$3 for any other drug in 2006.
- For years after 2006, the amounts specified earlier are adjusted for the annual percentage increase in the Consumer Price Index (CPI) as of September of the previous year, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or
- Under § 423.782(a)(2)(i), the copayment amount charged to: noninstitutionalized full-benefit dual eligible individuals who have income above 100 percent of the FPL, individuals with income under 135 percent of the FPL for years prior to 2024, or individuals with income under 150 percent of the FPL for years 2024 and thereafter.

On February 3, 2026, the Consolidated Appropriations Act, 2026 (CAA), Public Law 119–75, was enacted into law. Section 6219 of the CAA, titled “Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals,” amends section 1860D–14(a) of the Act to reduce the generic drug copayment from \$1 to \$0 for FBDE individuals with incomes that do not exceed 100 percent of the FPL, effective for plan years beginning on or after January 1, 2028. The provision also clarifies that the existing annual CPI

inflation adjustment methodology applies only to plan years before 2028 with respect to generic drug copayments for this population.

Currently, for plan years before January 1, 2028, FBDE individuals with incomes that do not exceed 100 percent of the FPL as described in § 423.782(a)(2)(iii), are subject to a \$1 copayment for generic drugs covered under Medicare Part D, adjusted annually for CPI. For plan year 2026, this amount is \$1.60 for generic drugs and \$4.90 for other covered Part D drugs, with no deductible, as reflected in the CY 2026 Resource and Cost-Sharing Limits for Low-Income Subsidy guidance issued October 31, 2025.

To implement section 6219 of the CAA, we are proposing to amend § 423.782(a)(2)(iii) to reflect that, for plan years beginning on or after January 1, 2028, the copayment for generic drugs for FBDE individuals with incomes that do not exceed 100 percent of the FPL is \$0. First, we are proposing to amend § 423.782(a)(2)(iii)(A) to specify that the cost-sharing rules in that paragraph are applicable to plan years before January 1, 2028. Second, we are proposing to redesignate paragraph (B) in § 423.782(a)(2)(iii) as paragraph (C) and add new paragraph (B) to specify that for plan years beginning on or after January 1, 2028, the copayment for generic drugs for FBDE individuals with incomes that do not exceed 100 percent of the FPL is \$0.

This proposal is a conforming change to existing regulatory text and would not alter the eligibility criteria, subsidy

structure, or any other cost-sharing parameters applicable to FBDE individuals. CMS is not proposing any changes to the copayment amounts applicable to the cost-sharing requirements for non-generic (brand-name) drugs or other covered Part D drugs for FBDE individuals. Specifically, the copayment for preferred multiple-source drugs and other covered drugs for FBDE individuals would continue to be adjusted annually for CPI in accordance with existing statutory and regulatory requirements. This proposal is narrowly tailored to implement the specific statutory directive in section 6219 of the CAA and does not introduce any discretionary policy changes.

We estimate approximately 6 million enrollees would be affected by these proposed changes, based on 2026 CMS enrollment data. We believe the proposed changes would impact the Medicare Trust Fund and individuals in two ways: elimination of the co-pay is expected to reduce out-of-pocket costs for affected enrollees, and the anticipated increase in generic drug utilization is expected to affect Medicare Trust Fund expenditures through transferring copay costs from the beneficiary to the Medicare program. This rule does not include a new collection of information; therefore, there is no change in paperwork burden to plans or individuals. Additional information is provided in the regulatory impact analysis in section IV.C.1. of this proposed rule.

B. REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026) (§§ 422.2, 422.111, 422.120, 422.123, 422.124, 422.202, 422.504, 422.2265, and 422.2267)

On February 3, 2026, in section 6220 of the Consolidated Appropriations Act, 2026 (CAA) (Pub. L. 119–75, H.R. 7148–484), Congress enacted the Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act. The REAL Health Providers Act amends sections 1851, 1852, and 1857 of the Act to establish new provider directory accuracy and accountability requirements for MA organizations, effective January 1, 2028, which is the beginning of contract year 2028. These statutory requirements include provider directory accuracy standards, accuracy score reporting, verification requirements, public transparency, and enrollee cost sharing protections. CMS is proposing to codify regulations to implement the REAL Health Providers Act legislation through this proposed rule. In addition to the statutory authority of the REAL Health

Providers Act, CMS is also relying on the statutory authorities of sections 1856(b)(1) and 1857(e)(1) of the Act to establish the standards needed to implement the REAL Health Providers Act that go beyond what is specifically addressed in section 6220 of the CAA. Section 1856(b)(1) of the Act provides that CMS shall establish by regulation other standards for MA organizations and plans consistent with, and to carry out, the Part C program. Likewise, section 1857(e)(1) of the Act authorizes CMS to specify additional contract terms as necessary and appropriate in the agreements that CMS enters into with each MA organization.

The REAL Health Providers Act directs the Secretary to strengthen requirements for the accuracy and public availability of provider directory information maintained by MA organizations offering specified MA plans. Existing regulations at § 422.111(m), finalized for plan years beginning on or after January 1, 2026, already establish a foundational framework requiring MA organizations to submit provider directory information to CMS/HHS for publication online in a format and manner determined by CMS (that is, on Medicare Plan Finder (MPF)), update that information within 30 days of becoming aware of a change, and attest to its accuracy no less than annually. As CMS explained when finalizing the § 422.111(m) requirements, these changes were intended to promote transparency and informed beneficiary choice by improving access to accurate online provider directory information for beneficiaries who are navigating their health care options (90 FR 45140). These goals closely parallel the enhanced accuracy and transparency requirements in the REAL Health Providers Act. Therefore, in implementing the REAL Health Providers Act, CMS intends to build directly upon, reinforce, and, where necessary, supplement this existing regulatory infrastructure, ensuring MA organizations have a clear and harmonized set of provider directory requirements, rather than creating a parallel, duplicative, or competing set of standards.

CMS is also actively developing a National Provider Directory (NPD), which is a centralized, standardized repository intended to serve as the authoritative public-facing platform for provider directory information across the entire health tech ecosystem. CMS expects that the provider directory data that it currently collects from MA organizations under the authority of § 422.111(m) will be compatible with

and may ultimately feed into the NPD infrastructure. Accordingly, CMS's proposed implementation of the REAL Health Providers Act requirements, through the existing § 422.111(m) framework, as described here in this section, is intended to be a deliberate and forward-looking approach that will position MA organizations, CMS, and the public to realize the full transparency benefits of the NPD as it develops. CMS believes this integrated approach, leveraging existing regulatory requirements, building towards a centralized national directory, and now incorporating the enhanced statutory mandates of the REAL Health Providers Act to verify data accuracy, represents the most administratively sound and least burdensome path to ensuring beneficiaries have access to accurate, reliable, and readily available provider directory information.

Taken together, these layered requirements—the existing § 422.111(m) data submission framework, the developing NPD infrastructure, and the new REAL Health Providers Act requirements regarding accuracy, verification, cost sharing protections, and public reporting mandates—work to support the larger health tech ecosystem to form a cohesive and mutually reinforcing regulatory architecture designed to ensure that beneficiaries can rely on provider directory information when making critical health care decisions. For example, the REAL Health Providers Act establishes statutory accuracy and verification standards specific to MA organizations, the MPF effort builds near-term data infrastructure for plan comparison, and the NPD advances a broader multi-payer directory accessible to all. While each of these initiatives operates on a distinct timeline and authority, they are intentionally designed to complement and reinforce one another. The accuracy scoring and verification framework required under the REAL Health Providers Act, for example, will serve to strengthen the integrity of the underlying provider data that both MPF and the NPD will likely come to depend upon, helping to ensure a consistent and reliable foundation for the larger health tech ecosystem.

CMS's proposed regulatory changes align with the statutory requirements of the REAL Health Providers Act. The proposals impact various existing sections under 42 CFR part 422, including §§ 422.2, 422.111, 422.120, 422.202, 422.504, 422.2265, and 422.2267. In addition, CMS is proposing to add two new sections: § 422.123—Provider directory accuracy requirements and § 422.124—Cost

sharing protections for reliance on incorrect provider directory information. CMS's proposals contained herein also consider feedback received from interested parties during the June 15, 2026, public meeting co-hosted by CMS and the Office of the National Coordinator for Health Information Technology (ONC), to gather input on implementing the REAL Health Providers Act. This virtual public meeting included participation from health care providers and suppliers, companies that specialize in relevant technologies (for example, provider data management, directory solutions, interoperability, verification tools, and data standards), health insurers (including MA organizations and other health plans), and patient advocates. CMS's proposals also considered written feedback from interested parties submitted after the public meeting.

During the June 15, 2026, public meeting, participants broadly supported CMS's efforts to improve provider directory accuracy while emphasizing the importance of implementing these requirements in a manner that minimizes administrative burden and promotes standardized, interoperable data exchange. Participants consistently identified provider practice locations, specialty information, acceptance of new patients, telehealth capabilities, and provider participation status as among the most challenging provider directory data elements to maintain accurately. Several participants recommended establishing standardized definitions for key provider directory information, which informed CMS's proposal to establish consistent provider directory information requirements and definitions.

Interested parties also expressed strong support for a centralized, authoritative source of provider directory information and encouraged CMS to leverage interoperability standards, existing CMS data sources, and emerging technologies to improve directory accuracy while reducing duplicative verification activities. These comments are consistent with CMS's proposed approach of building upon the existing provider directory submission framework under § 422.111(m), supporting the development of the NPD, and permitting the use of CMS-maintained data sources and verification methods. In addition, interested parties emphasized the importance of transparent, repeatable verification methodologies and encouraged CMS to recognize verification approaches that reduce burden on both MA organizations and providers.

Interested parties also discussed prioritizing provider specialty types with historically higher rates of directory inaccuracies, including behavioral health providers, and recommended that CMS focus verification and oversight efforts where they would have the greatest impact on beneficiary access to care. These comments informed CMS's proposals to identify high-inaccuracy provider specialty types and develop a weighted provider directory accuracy scoring methodology that considers both the relative importance of provider directory information to beneficiary access and the administrative burden associated with analysis. Finally, interested parties highlighted the importance of beneficiary protections when provider directory information is inaccurate, reinforcing CMS's proposal to implement the enrollee cost sharing protections established under the REAL Health Providers Act.

Overall, these proposals support the Administration's goals of improving health care transparency, strengthening beneficiary access to accurate provider information, ensuring that beneficiaries are protected when they rely on information furnished by MA organizations, and integrating with health tech ecosystem initiatives. Specifically, these proposed changes align with the June 24, 2019, Executive Order 13877, "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (hereinafter referred to as E.O. 13877) and the February 25, 2025, Executive Order 14221, "Making America Healthy Again by Empowering Patients With Clear, Accurate, and Actionable Healthcare Pricing Information" (hereinafter referred to as E.O. 14221). Through these proposed codifications implementing the REAL Health Providers Act, CMS seeks to promote provider directory accuracy and accountability among MA organizations to ensure that beneficiaries are provided with clear, accurate information on the network of providers available to meet their health care needs.

1. Definitions (§ 422.2)

CMS is using the existing definition of "provider" under § 422.2 for purposes of this proposed regulation, unless otherwise indicated. Pursuant to § 422.2, a provider is (1) any individual who is engaged in the delivery of health care services in a state and is licensed or certified by the state to engage in that activity in the state; and (2) any entity that is engaged in the delivery of health care services in a state and is licensed or certified to deliver those services if

such licensing or certification is required by state law or regulation.

To use consistent terminology throughout all impacted regulation sections, CMS proposes adding several new provider directory related definitions to § 422.2. The REAL Health Providers Act amended the disclosure requirements at section 1852(c) of the Act to add new subsection (c)(3) entitled "Provider Directory Accuracy." The statute provides that the obligations under this subsection will apply to "specified MA plans" as defined in section 1852(c)(3)(C) of the Act. Thus, consistent with section 1852(c)(3)(C) of the Act, CMS proposes to define "specified MA plan" at § 422.2 as: (1) a network-based plan as defined in § 422.2—which includes MA plans that are coordinated care plans (for example, health maintenance organizations, provider-sponsored organizations, regional or local preferred provider organizations (PPOs), and specialized MA plans for special needs individuals), network-based Medicare Savings Account plans, or cost plans—or (2) an MA private fee-for-service (PFFS) plan that meets the access standards under § 422.114, in whole or in part, through entering into contracts or agreements with a network of providers. In other words, the proposed definition of "specified MA plan," and the related proposed requirements for specified MA plans described in this proposed rule, would apply to all types of MA plans except non-network regional PPOs that meet access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts. Likewise, the proposed definition of "specified MA plan" and the related proposed requirements for specified MA plans, would not apply to Program of All-Inclusive Care for the Elderly (PACE) plans.

In addition, section 1852(c)(3)(B) of the Act defines "provider directory information" as "information enrollees may need to access covered benefits from a provider with which such organization offering such plan has an agreement for furnishing items and services covered under such plan, such as name, specialty, contact information, primary office or facility addresses where items or services are furnished, whether the provider is accepting new patients, accommodations for people with disabilities, cultural and linguistic capabilities, and telehealth capabilities." Accordingly, CMS proposes to define "provider directory information" at § 422.2 to conform with this section of the Act as "information enrollees may need to access covered benefits from a provider with which an

MA organization offering a specified MA plan has an agreement for furnishing items and services covered under such plan, including, at a minimum, all of the following: (1) provider name; (2) specialty; (3) contact information, including telephone number(s); (4) primary office or facility address(es) where covered items or services are furnished; (5) whether the provider is accepting new patients; (6) accommodations for people with disabilities; (7) cultural and linguistic capabilities; (8) telehealth capabilities; and (9) common ownership or control disclosure.”

This proposed regulatory definition captures all the elements of the statutory definition and includes one additional element—common ownership or control disclosure. CMS interprets the “such as” in section 1852(c)(3)(B) of the Act to mean that the data elements specifically listed in the statute are required, but not exhaustive of the types of information that may be considered “provider directory information” (that is, information that enrollees may need to access covered benefits from a contracted provider) for purposes of the requirements provided under the REAL Health Providers Act. CMS believes that common ownership or control disclosure is necessary to inform plan and provider choice because vertical integration may affect care delivery arrangements, referral patterns, and negotiated charges or payment arrangements. Greater transparency regarding common ownership or control may also be useful for beneficiaries, caregivers, State Health Insurance Assistance Program (SHIP) counselors, agents, brokers, researchers, and other entities assisting beneficiaries or evaluating MA provider networks. In the MA marketplace, provider networks are a central feature beneficiaries use to compare plan options, assess whether they can access preferred providers, and understand how care may be delivered within a plan’s network. Information indicating that a network provider, provider group, facility, or supplier is under common ownership or control with the MA organization or its parent organization may provide important context about the relationship between the plan and the providers from whom enrollees may obtain covered services. For example, such information may help beneficiaries and those assisting them understand whether a plan’s network includes providers that are part of the same corporate family as the MA organization, which may be relevant to evaluating provider choice, potential care coordination arrangements, referral

pathways, and the structure of the network. CMS also believes that this information may promote broader transparency in the MA marketplace by allowing researchers, policymakers, and other interested parties to better assess the prevalence and effects of vertical integration across MA networks, including how common ownership or control relationships may relate to network design, access to care, utilization patterns, and beneficiary decision-making.

Under the proposed definition for “provider directory information” at § 422.2, CMS proposes for common ownership or control disclosures to include any network provider, provider group, facility, or supplier that is owned or controlled, in whole or in part, directly or indirectly, by the MA organization, by the MA organization’s parent organization, by a subsidiary or affiliate of the MA organization, or by any entity that is under common ownership or control with the MA organization. CMS considers a provider to share ownership or control with an MA organization if the provider and the MA organization are directly or indirectly owned or controlled by the same parent organization, ultimate parent organization, holding company, or other controlling entity, regardless of whether the MA organization itself directly owns the provider. For example, an MA organization may be one subsidiary of a parent or holding company, while a physician group, hospital system, or other network provider may be owned by a separate subsidiary of the same parent or holding company. In this scenario, the MA organization may not directly own the provider, and the provider may not be legally organized under the MA organization itself. However, because both the MA organization and the provider are owned or controlled, directly or indirectly, by the same parent or holding company, CMS would consider the provider to be under common ownership or control with the MA organization for purposes of the proposed provider directory disclosure requirement. The provider directory disclosure could state: “This provider is under common ownership or control with [MA organization name or parent organization name].”

As another example, an MA organization’s parent organization may own a health care services subsidiary, and that subsidiary may own, control, or partially own a provider group through one or more intermediate entities, and such provider group may be in the MA plan’s network. The provider group may operate under a different trade name,

may contract with multiple health plans, and may not be directly owned by the MA organization. Nevertheless, if the MA organization and the provider group are connected through indirect ownership or control by the same parent organization, affiliate, subsidiary, or other controlling entity, then CMS would consider the provider group to be under common ownership or control with the MA organization for purposes of the provider directory disclosure requirement. In that circumstance, the directory could identify the relationship using standardized language, such as: “This provider group is under common ownership or control with [MA organization name or parent organization name].” CMS solicits comments on the proposed model language that should be used in the disclosure statement and whether different versions of the statement would be necessary to accommodate different types of ownership or affiliations. With this proposed model language, CMS aims to capture these various business relationships appropriately but also provide the information in a simple and understandable manner for beneficiaries.

This requirement to disclose common ownership or control would not alter, or otherwise affect any existing or future standards, definitions, reporting obligations, or analyses related to MA bid development, medical loss ratio reporting, related-party disclosures, financial audits, or any other program integrity, payment, accounting, or oversight requirements outside of this provider directory disclosure construct. CMS solicits comments on whether these examples appropriately describe the types of direct, indirect, affiliate, subsidiary, parent, and common-control relationships that should be included in the proposed provider directory disclosure requirement, and whether additional examples or exclusions would be helpful for MA organizations, providers, beneficiaries, and other users of provider directory information.

CMS notes that the proposed provider directory element of “accommodations for people with disabilities” is referring to notations in the provider directory for provider listings in which accommodations for people with disabilities exist. Such accommodations may include physical accessibility features (such as accessible entrances with ramps, elevators, accessible exam rooms and tables, accessible medical equipment, and accessible parking), auxiliary aids and services, and other necessary accommodations. MA organizations must adhere to all current

federal laws and regulations concerning accommodations for people with disabilities, including Section 504 of the Rehabilitation Act of 1973, Title II of the Americans with Disabilities Act (ADA) of 1990, and Section 1557 of the Affordable Care Act of 2010. Questions regarding this topic should be directed to the HHS Office for Civil Rights (OCR).

In addition, CMS notes that the proposed provider directory element of “cultural and linguistic capabilities” based on the language in the Act is similar to existing language at § 422.111(b)(3)(i). However, CMS proposes to adopt the terminology used by Congress for “cultural and linguistic capabilities” without retaining the additional language in current § 422.111(b)(3)(i) specifying that “each provider’s” cultural and linguistic capabilities includes “languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider’s office.” In light of the intervening statutory requirement enacted by Congress, CMS believes it is appropriate to implement section 1852(c)(3)(B) of the Act using the terminology selected by Congress. This approach retains the requirement for MA organizations to include providers’ cultural and linguistic capabilities in their provider directories and also reflects changes in Federal policy since publication of the April 12, 2023, Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule. Executive Order 14151, “Ending Radical and Wasteful Government DEI Programs and Preferencing,” directed agencies, consistent with applicable law, to review Federal policies and regulations adopted in furtherance of prior diversity, equity, inclusion, and accessibility initiatives and to align agency actions with the policies established by that order. CMS recognizes that providers may have a variety of cultural and linguistic capabilities that could be included in an MA organization’s provider directory. Therefore, by removing this additional language, CMS is providing added flexibility regarding the types of cultural and linguistic capabilities that MA organizations can include in their provider directories. As proposed, CMS intends to allow MA organizations to include information beyond the examples identified in § 422.111(b)(3)(i). This flexibility would allow MA

organizations to highlight capabilities that respond to the specific needs of their enrollees and help beneficiaries identify providers who can meet those needs.

CMS also proposes to add a definition for “provider directory” to § 422.2, which would pull together provider directory categories of information (§ 422.111(b)(3)(i)(A), (b)(3)(i)(B), and (b)(12)) and be defined as “for specified MA plans, as defined in this section, the publicly available listing, maintained and distributed by an MA organization pursuant to § 422.2267(e)(11), of providers that are currently contracted and participating in that MA plan’s provider network, and containing the information under § 422.111(b)(3)(i)(A), (b)(3)(i)(B), and (b)(12).” CMS’s proposed definition for “specified MA plan” would apply here. Note that CMS is proposing to include the cross-reference to § 422.111(b)(3)(i)(B) in this proposed definition of “provider directory,” which eliminates the need to refer to “provider directory information” in this definition because CMS’s proposed changes to § 422.111(b)(3)(i)(B) (discussed in section II.B.11. of this proposed rule) include a cross-reference to the definition of “provider directory information.”

Finally, CMS proposes to define “provider directory accuracy score” at § 422.2 as “the score reflecting the accuracy of provider directory information calculated and reported in accordance with § 422.123(d).” Regarding the cross-references to §§ 422.111(b)(12) and 422.123(d) in these two new proposed definitions, these are two new proposed sections of the regulation which CMS discusses in sections II.B.4., II.B.5., II.B.6., and II.B.11. of this proposed rule. CMS solicits comments on these proposed changes to definitions at § 422.2.

2. Provider Directory Verification Requirements (§§ 422.123(a) and (b), 422.2265(b)(3) and (b)(15), and 422.111(h)(2))

The REAL Health Providers Act’s addition of section 1852(c)(3) of the Act establishes new provider directory requirements for plan year 2028 and subsequent plan years, in which each MA organization offering a specified MA plan shall, for each specified MA plan offered by the organization, do the following: (1) maintain, on a publicly available internet website, an accurate provider directory that includes provider directory information; (2) not less frequently than once every 90 days (or, in the case of a hospital or any other facility determined appropriate by the

Secretary, at a lesser frequency specified by the Secretary but in no case less frequently than once every 12 months), verify the provider directory information of each provider listed in such directory and, if applicable, update such information; (3) if the organization is unable to verify such information with respect to a provider, include in such directory an indication that the information of such provider may not be up to date; and (4) remove a provider from such directory within 5 business days if the organization determines that the provider is no longer a provider participating in the network of such plan.

To implement these new requirements of section 1852(c)(3) of the Act, CMS proposes to add new § 422.123—Provider directory accuracy. Within new proposed § 422.123, paragraph (a) would set forth the applicability of the section to each MA organization offering a specified MA plan for contract year 2028 and subsequent contract years. Although the statute uses the term “plan year,” the customary term that CMS uses is “contract year,” therefore, CMS proposes language using the term “contract year” throughout the proposed regulations. To codify section 1852(c)(3)(A)(i) of the Act, CMS proposes to amend § 422.2265(b)(3) to require that an MA organization’s website includes an accurate provider directory for each specified MA plan that includes provider directory information for each provider that is currently contracted and participating in the plan’s provider network. CMS also proposes a slight modification to the existing regulatory language at § 422.2265(b)(3), which currently reads: “A PDF or copy of a printable provider directory.” To ensure greater clarity in terminology, CMS proposes to revise this phrase to read as follows: “a PDF or otherwise printable electronic copy of the provider directory.” Section II.B.3. of this proposed rule includes a more detailed discussion of the proposed requirements for updating this version of the provider directory.

In conjunction with the proposed changes at § 422.2265(b)(3), and in line with the January 31, 2025, Executive Order 14192, “Unleashing Prosperity Through Deregulation,” CMS is taking the opportunity to streamline existing regulations. CMS proposes to make conforming changes to § 422.111(h)(2) to cross-reference §§ 422.2265, 422.120(a), and 422.2267(d) and remove duplicative information that is already addressed by the aforementioned regulations. Specifically, at § 422.111(h)(2), CMS proposes to require MA organizations to

have a publicly available internet website that complies with the website requirements in §§ 422.2265 and 422.120(a) and state that posting copies of required materials on the website does not relieve the MA organization of its responsibility to provide hard copies to enrollees upon request in accordance with § 422.2267(d) or when required by CMS. This proposed change would remove the existing reference to § 422.111(b) in § 422.111(h)(2) and replace it with a reference to the website requirements at § 422.2265. All the contents of a plan description under § 422.111(b) are already required on MA organizations' websites per § 422.2265, except existing § 422.111(b)(9), the quality improvement program. To preserve this requirement, CMS proposes to add a new paragraph (b)(15) to § 422.2265 to require an MA organization's website to include a description of the quality improvement program required under §§ 422.152 and 422.111(b)(9). The proposed change to § 422.111(h)(2) would also remove duplicative information about hardcopy requirements for required materials (such as the evidence of coverage, provider directory, and summary of benefits) and instead include a cross-reference to these requirements which are already outlined at § 422.2267(d).

To codify section 1852(c)(3)(A)(ii) and (iii) of the Act, CMS proposes to add new § 422.123(b) to set forth the new provider directory verification requirements. Aligning with the statute, at new proposed § 422.123(b)(1), CMS proposes to require each MA organization offering a specified MA plan to verify the provider directory information of each provider listed in that specified MA plan's provider directory not less frequently than once every 90 days, except in the case of hospitals and other facilities as listed in § 422.116(b)(2)(i), (iv), and (v)—that is, acute inpatient hospitals, critical care services (intensive care units), and surgical services (outpatient or ambulatory surgery center). For these excepted hospitals and other facilities, CMS proposes to require each MA organization offering a specified MA plan to verify the provider directory information of these entities not less frequently than once every 12 months. The statute provides CMS with discretion to impose verification requirements for hospitals or any other facility determined appropriate by the Secretary at a lesser frequency than once every 90 days (as is the case for other providers) but at a frequency no less than once every 12 months. At this time, CMS is proposing a 12-month

verification frequency for these entities. CMS selected these three types of entities because CMS believes that data for these specific entities is generally more static, as they may not move locations as often as other providers or facilities given their size and facility requirements, therefore, verifying the information at least every 12 months is sufficient for these types of entities. This policy approach would also limit some of the burden associated with verification on both MA organizations and these facilities. In addition, CMS's proposed reference to hospitals and other facilities listed in § 422.116(b)(2)(i), (iv), and (v) is appropriate because MA organizations are familiar with this list of facilities for purposes of network adequacy. CMS seeks comments specifically on the proposed selection of other facilities listed in § 422.116(b)(2)(i), (iv), and (v) for the 12-month verification requirement. For all providers listed in the provider directory, CMS proposes that the MA organization must comply with the appropriate verification frequency (90 days or 12 months) and update the provider directory in accordance with CMS's updating requirements, if updates are needed. Provider directory updating requirements are discussed in section II.B.3. of this proposed rule.

Next, at new proposed § 422.123(b)(2), CMS proposes to require the MA organization to use one or more CMS-specified provider directory verification methods to meet the provider verification requirements, including verification using internal plan information, verification via telephone or email, verification using provider attestations, verification using data sources maintained by CMS, claims data, or other verification methods specified by CMS. By including internal plan information as a proposed CMS-specified provider directory verification method, CMS is referring to information such as current, accurate provider rosters or recent claims information. Regarding data sources maintained by CMS, CMS means provider data repositories, such as the National Plan and Provider Enumeration System (NPPES), and provider directory databases, such as the NPD, that are maintained by CMS. By including claims data, CMS is referring to data containing information on recent claims between the contracted provider and the MA organization.

By including data sources maintained by CMS and other verification methods specified by CMS in this proposed list, CMS would retain the flexibility to specify additional acceptable, CMS-

approved verification methods in technical guidance. CMS is aware that this is a space where technology and the use of artificial intelligence is quickly evolving and CMS's work on the NPD is ongoing, and including this flexibility in proposed § 422.123(b)(2) would enable CMS to respond more quickly to advancements in verification methods, ultimately providing MA organizations with more options for meeting their provider directory verification obligations. CMS would provide technical guidance as necessary.

CMS anticipates that MA organizations may need to use more than one verification method to verify all the elements of provider directory information in the proposed provider directory verification requirements. For example, CMS recognizes that MA organizations may be accustomed to using NPPES. However, NPPES has both benefits and limitations, including the fact that certain provider directory information may not be available in NPPES, such as whether a provider is accepting new patients. As such, there will likely be a need for MA organizations to supplement use of NPPES with other verification method(s) to verify all the elements of provider directory information that CMS requires. In addition, CMS is also actively developing the NPD, which is intended to be a centralized, standardized repository meant to serve as the authoritative public-facing platform for provider directory information across the entire health tech ecosystem. CMS anticipates that once the NPD is fully operational, MA organizations might be able to use this source for verification, as it falls under the category of a data source maintained by CMS.

CMS issued guidance through the Health Plan Management System (HPMS) on January 3, 2020, and June 29, 2022, about the use of NPPES for determining the accuracy of provider directory data in CMS's various monitoring and enforcement activities. In the January 3, 2020, HPMS memorandum, CMS stated that the agency, in its monitoring and enforcement activities, would employ discretion should it uncover errors in directories that are consistent with NPPES data that has been updated or certified between January 1 and April 30, 2020, so long as any errors identified are corrected within 30 days. In the June 29, 2022, HPMS memorandum, CMS stated that it would continue to use discretion while monitoring and reviewing organizations' online provider directories for compliance and enforcement action and that during

compliance reviews, if CMS finds an error in an organization's online provider directory and the error matches the information in NPPEs, then that error will not be considered an "error" for purposes of compliance so long as the organization contacts the provider, whose information was incorrect, within 30 days to encourage the provider to correct their information in NPPEs. By proposing to include NPPEs as one of the verification methods that MA organizations may use to verify provider directory information, and also because there would be other verification methods that MA organizations may use, CMS would not need to continue to use this discretion for compliance and enforcement actions if these provisions are finalized as proposed. Also, since issuing these memoranda, the landscape related to provider directories in MA has shifted due to the REAL Health Providers Act and CMS's efforts to develop the NPD. Therefore, if these provisions are finalized as proposed, CMS intends to rescind this previously issued guidance (in both the January 3, 2020, and June 29, 2022, HPMS memoranda) regarding MA organizations' usage of NPPEs for purposes of verifying provider directory accuracy.

CMS notes that, in developing the proposal for the 90-day/12-month provider directory verification requirement at new proposed § 422.123(b)(2), CMS considered limiting which verification method(s) may be used by MA organizations for which provider directory elements. Including such limitations may potentially impose additional burden on MA organizations. At this time, CMS is not proposing any such limitations on MA organizations' use of the proposed verification method(s) for fulfilling their 90-day/12-month provider directory verification obligations as described in new proposed § 422.123(b)(1)(i) and (ii). However, as discussed in section II.B.5. of this proposed rule, at new proposed § 422.123(d)(3)(i), CMS is proposing to limit what verification method(s) may be used by MA organizations to evaluate the accuracy of certain provider directory data elements for purposes of calculating the estimated provider directory accuracy score (please refer to that section of this proposed rule for a more detailed discussion). CMS solicits comments on the considerations and proposals surrounding limiting verification approaches, for both new proposed § 422.123(b)(2) and (d)(3)(i). In addition, CMS intends to identify certain best practices in technical guidance, such as which verification

methods might be more appropriate or reliable for the proposed 90-day/12-month provider directory verification requirement, depending on the particular provider directory data elements being verified.

To implement section 1852(c)(3)(A)(iii) of the Act, at § 422.123(b)(3), CMS proposes to require that if the MA organization is unable to verify provider directory information with respect to a provider during the applicable verification cycle, then the MA organization must include in the provider directory a clear indication that the information of such provider may not be up to date. An example of language that CMS believes would be sufficient for this proposed indicator is: "The provider's information may not be up to date." If § 422.123(b)(3) is finalized as proposed, then CMS intends to update the Medicare Advantage and Section 1876 Cost Plan Provider Directory Model and Instructions with similar template language for the indicator. If the MA organization subsequently verifies or updates the information, then the MA organization must remove or revise the indicator consistent with CMS's provider directory updating requirements.

Finally, per existing statutory authority under section 1856(b)(1) of the Act to establish by regulation other standards for MA organizations consistent with, and to carry out, the Part C program, CMS is proposing, at new proposed § 422.123(b)(4), to require that each MA organization offering a specified MA plan must include a term in their contract with each contracted provider for a specified MA plan, obligating the contracted provider to maintain current and accurate provider directory information as defined in proposed § 422.2. The purpose of this new proposed contract requirement is to ensure that when the MA organization verifies provider directory information in accordance with proposed § 422.123(b), the information the MA organization obtains from each contracted provider is more likely to be current and accurate. This proposed contract requirement is intended to improve the reliability of the data that MA organizations obtain directly from their contracted providers, specifically the type of data collected using the first four CMS-specified verification methods outlined at proposed § 422.123(b)(2)(i) through (iv), which are internal plan information, telephonic verification, email verification, and provider attestations. CMS believes that this proposed provider contract term is necessary to assist MA organizations in carrying out successful verification

efforts, which would ultimately support the broader effort to ensure accurate provider directories.

In summary, to implement several aspects of the REAL Health Providers Act, CMS is proposing the provider directory accuracy applicability requirement at new proposed § 422.123(a), verification requirements at new proposed § 422.123(b), proposed changes to the website requirement at § 422.2265(b)(3), a streamlining of existing regulations at § 422.111(h)(2), and a preservation of the existing requirement for a description of the quality improvement program on an MA organization's website at new proposed § 422.2265(b)(15). CMS solicits comments on these proposed changes.

3. Provider Directory Updating Requirements (§§ 422.123(c) and 422.2267(e)(11)(iv))

Implementation of the REAL Health Providers Act presents CMS with the opportunity to streamline other existing provider directory regulations, including rules around updating provider directories. After considering the proposed layout of the new rules for provider directory accuracy, CMS determined it would be prudent to move the existing updating requirements for provider directories to new proposed § 422.123, for purposes of logic and ease of reading. Therefore, CMS is proposing to move the updating requirements from § 422.2267(e)(11)(iv) to new proposed § 422.123(c). CMS is not changing the basic 30-day provider directory updating requirement, but CMS is proposing some changes in order to implement certain requirements of the REAL Health Providers Act. The current provider directory regulations apply to MA plans with provider networks, all of which are included in the proposed definition of "specified MA plan."

The MA organization will still be required to update both the online provider directory and the PDF or otherwise printable electronic copy of the provider directory (as specified in proposed § 422.2265(b)(3)) within at least 30 days of receiving information requiring update, except that a provider must be removed from the directory no later than 5 business days after the MA organization determines that the provider is no longer participating in the specified MA plan's network. CMS is proposing to move this requirement to new proposed § 422.123(c)(1). This proposed 5-business-day updating requirement would apply to both the online provider directory and the PDF or otherwise printable electronic copy of the provider directory (as specified in proposed § 422.2265(b)(3)). In other

words, if this requirement is finalized as proposed, MA organizations would be required to update the PDF or otherwise printable electronic copy version of their provider directory within 5 business days, but this would not mean printing new physical hardcopies since the PDF or otherwise printable electronic copy of the provider directory is required to be posted on the MA organization's website. This 5-business-day updating requirement would apply to PDF or otherwise printable electronic copy of the provider directory posted on the MA organization's website and would not require an MA organization to mail a revised physical hardcopy directory to an enrollee within 5 business days. As discussed further later, for enrollees who have requested a physical hardcopy provider directory, CMS is separately proposing at § 422.123(c)(2) to require MA organizations to send a quarterly addendum containing updates to the provider directory. This quarterly addendum would provide a regular mechanism for keeping enrollees who rely on a previously furnished physical hardcopy directory informed of subsequent directory changes without requiring MA organizations to mail a revised physical hardcopy directory each time an update is made.

To codify section 1852(c)(3)(A)(iv) of the Act, at § 422.123(c)(4) CMS proposes to require that the MA organization must remove a provider from the provider directory no later than 5 business days after the date on which the MA organization determines that the provider is no longer participating in the network of the specified MA plan. This would be the only proposed exception to the 30-day provider directory updating requirement at new proposed § 422.123(c)(1).

In addition, although the REAL Health Providers Act does not include a specific timeframe for updating physical hardcopy provider directories, CMS would like to take the opportunity through this proposed rule to further clarify the policies regarding physical hardcopy updates via addenda. Currently, § 422.2267(e)(11)(iv)(B)(2) states that hardcopy directories that include separate updates via addenda are considered up to date. CMS has reconsidered this policy and determined that it would be beneficial to specify a regular cadence for updating physical hardcopy directories to avoid ambiguity or misinterpretation by MA organizations. Specifically, CMS proposes to require MA organizations to send a quarterly addendum containing updates to all enrollees who have requested a physical hardcopy provider

directory. Sending a quarterly update only to those enrollees who have requested a physical hardcopy directory would meet the requirements for keeping physical hardcopy directories updated and avoid the need for MA organizations to mail updated physical hardcopy directories on a monthly basis, thus reducing burden. This policy would be a supportive beneficiary protection because it would keep enrollees informed with a predictable and regular cadence of updates if they are accustomed to using a physical hardcopy directory, and it would protect enrollees from making a misinformed decision based on an outdated version of the physical hardcopy directory. CMS proposes to add this requirement regarding the quarterly addendum for physical hardcopy provider directories at new proposed § 422.123(c)(2).

In addition, while CMS believes it is unlikely for plans or agents/brokers to use physical hardcopy directories at marketing events (and instead refer to or show prospective enrollees the online provider directory), CMS clarifies that if plans or agents/brokers do plan to distribute physical hardcopy directories, then they would need to print out the PDF or otherwise printable electronic copy of the provider directory that exists on the MA organization's website and use that current, up-to-date version if needed for physical distribution to prospective enrollees. This would ensure that prospective enrollees have access to the most updated provider directory that exists at that time.

Furthermore, due to the point-in-time nature of physical hardcopy directory updates and the fact that if CMS finalizes the proposed quarterly addenda policy then enrollees receiving a physical hardcopy directory would only receive four updates per year, CMS proposes to require that MA organizations include a disclaimer on the physical hardcopy provider directory that recommends beneficiaries check the online provider directory or contact the MA organization for the latest updates. CMS proposes to add this requirement at new proposed § 422.123(c)(3). CMS believes this type of disclaimer is essential to keep all beneficiaries (both prospective enrollees and current enrollees) informed and aware that the online directory is likely the most reliable version because of the ease and timeliness of making electronic updates. This would ensure that all beneficiaries have access to the most current and accurate information about the plan's provider network.

These proposed changes related to provider directory updating

requirements at new proposed § 422.123(c) would replace and supplement existing updating requirements at § 422.2267(e)(11)(iv). Accordingly, CMS is proposing to amend § 422.2267(e)(11)(iv) to require that the provider directory be verified and updated in accordance with § 422.123(b) and (c) (for contract year 2028 and subsequent contract years).

In summary, CMS is proposing several changes to the provider directory updating requirements, including moving existing updating requirements from § 422.2267(e)(11)(iv) to § 422.123(c)(1), implementing section 1852(c)(3)(A)(iv) of the Act at § 422.123(c)(4), adding new requirements related to physical hardcopy directories at § 422.123(c)(2) and (c)(3), and updating § 422.2267(e)(11)(iv) to refer to § 422.123(b) and (c). CMS solicits comments on these proposed changes.

4. Provider Directory Accuracy Analysis and Sampling Methodology (§ 422.123(d)(1) and (2))

In addition to provider directory verification and updating requirements, the REAL Health Providers Act establishes new requirements regarding provider directory accuracy. Section 1857(e)(6)(A) of the Act requires that beginning with plan years beginning on or after January 1, 2028, each MA organization must conduct an annual analysis estimating the accuracy of the provider directory information of each specified MA plan using a random sample of providers included in such provider directory. Further, section 1857(e)(6)(A)(i)(I) and (II) of the Act states that this sample shall include a random sample of each specialty of providers with a high inaccuracy rate of provider directory information relative to other specialties of providers, as determined by the Secretary, and one type of specialty may be providers specializing in mental health or substance use disorder treatment. CMS believes it is important that the provider directory accuracy analysis focus on a blend of provider specialty types including those that are known to have a high inaccuracy rate, as required by the statute, but to further include other provider specialty types that do not fall within the high inaccuracy rate criteria. Following this process allows CMS to continue to test and identify areas of inaccuracy as they apply to provider specialty types.

To implement the new requirements of section 1857(e)(6)(A) of the Act, CMS proposes to add new § 422.123(d)(1) to establish the annual accuracy analysis requirement and § 422.123(d)(2) to set

forth the sampling frame and methodology requirements. At new proposed § 422.123(d)(1), beginning with contract years beginning on or after January 1, 2028, each MA organization would be required to conduct an annual analysis estimating the accuracy of all provider directory information, except for “provider name,” “cultural and linguistic capabilities,” and “common ownership or control disclosure,” of each specified MA plan. CMS’s proposed definitions for “provider directory information” and “specified MA plan” at § 422.2 would apply here. CMS proposes to add the sampling frame and methodology requirements at new proposed § 422.123(d)(2), stating that the analysis must use a random sample of provider records and proposes specifying provider specialty types with high provider directory inaccuracy rates at new proposed § 422.123(d)(2)(ii). When determining provider specialty types with high provider directory inaccuracy rates, at new proposed § 422.123(d)(2)(i), CMS proposes that CMS will consider all provider specialty types included in the Medicare specialty codes and National Uniform Claim Committee (NUCC) taxonomy and may consider other provider specialty types and providers furnishing supplemental benefits.

In alignment with the statute, at new proposed § 422.123(d)(2)(ii)(A), CMS proposes to identify mental health or substance use disorder treatment provider specialty types specified by CMS as provider specialty types with high provider directory inaccuracy rates. Studies conducted regarding behavioral health providers support CMS’s inclusion of mental health or substance use disorder treatment as a provider specialty type with high provider directory inaccuracy rates. In 2025, the HHS Office of Inspector General (OIG) found that, on average, 55 percent of behavioral health providers listed in plans’ networks did not provide a single service to enrollees in 2023 (that is, were inactive providers).¹ OIG also conducted a survey of a random sample of inactive providers from both MA and Medicaid managed care plans and found that 72 percent of the inactive providers should not have been listed as network providers in the plan directories.² Other studies

conducted on provider networks outside of MA have also found issues with mental health providers in provider networks.³

CMS proposes to identify providers that fall under this provider specialty type in technical guidance using two sources, as listed in new proposed § 422.123(d)(2)(i)(A). The primary source CMS anticipates using is the Medicare physician/non-physician practitioner specialty codes identified in section 10.8 of chapter 26 of the Medicare Claims Processing Manual. Physicians self-designate their Medicare physician specialty on their Medicare enrollment application or on the internet-based Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Non-physician practitioners are assigned a Medicare specialty code when they enroll based on their profession. Specialty codes are used by CMS for programmatic and claims processing purposes. For example, these specialty codes are used in MA to identify provider specialty types for purposes of network adequacy reviews. CMS understands that the industry standard that is used for provider specialty types is the NUCC taxonomy, and CMS publishes a crosswalk between the Medicare specialty codes and the NUCC taxonomy codes semiannually.⁴ Regarding the second source that CMS would use to determine the provider specialty types with high provider directory inaccuracy rates, in addition to the Medicare specialty codes, CMS anticipates considering the use of additional codes from the NUCC taxonomy where appropriate to augment the Medicare specialty codes. CMS seeks comments on this proposal.

CMS intends to identify the specific Medicare specialty codes and/or NUCC taxonomy codes that correspond to the provider specialty types with high provider directory inaccuracy rates, as described in proposed § 422.123(d)(2)(ii)(A), in annual technical guidance. CMS intends to

propose the codes in draft guidance and request comments on the proposed codes. CMS then intends to issue final annual technical guidance with the final codes which will incorporate stakeholder feedback on what was proposed. CMS anticipates that the Medicare specialty codes that will meet the requirement at new proposed § 422.123(d)(2)(ii)(A) are 26 (Psychiatry), 27 (Geriatric Psychiatry), 86 (Neuropsychiatry), 62 (Psychologist), 68 (Clinical Psychologist), 80 (Licensed Clinical Social Worker), 79 (Addiction Medicine), D5 (Opioid Treatment Program), E1 (Marriage and Family Therapist), and E2 (Mental Health Counselor). CMS also is considering proposing some NUCC taxonomy codes in addition to these Medicare specialty codes, such as 104100000X (Behavioral Health & Social Service Providers/Social Worker), 101Y00000X (Behavioral Health & Social Service Providers/Counselor), and 363LP0808X (Physician Assistants & Advanced Practice Nursing Providers/Nurse Practitioner, Psychiatric/Mental Health). CMS seeks comments on the anticipated inclusion of these Medicare specialty codes and NUCC taxonomy codes in technical guidance and also whether there are other Medicare specialty codes or NUCC taxonomy codes that CMS should consider including in technical guidance. CMS also notes that providers can have many NUCC taxonomy codes and thus anticipates proposing that if the taxonomy codes match any of the NUCC taxonomy codes that a provider has, then they would be identified as a provider specialty type with high provider directory inaccuracy rates. CMS seeks comments on whether a subset of the NUCC taxonomy codes that a provider has should be considered instead of all of them, and, if so, how that subset may be defined.

CMS also considered using the network adequacy provider specialty types as defined under § 422.116(b)(1)(xxviii), (b)(1)(xxix), and (b)(2)(xiv) to define the scope of “mental health or substance use disorder treatment provider specialty types” as described in 422.123(d)(2)(ii)(A), but CMS identified some drawbacks to this alternative. The requirements at § 422.116(b) do not include all provider and facility specialty types but only those used for purposes of MA network adequacy reviews. Also, our proposal to primarily use the Medicare specialty codes aligns with the requirements at § 422.116(b), as those are also based on the Medicare specialty codes. Further, CMS aims to ensure the comparability of the resulting provider directory

Plans Have Limited Behavioral Health Provider Networks and Inactive Providers. Office of Inspector General: October 2025. Available from: <https://oig.hhs.gov/documents/evaluation/11233/OEI-02-23-00540.pdf>.

³ For example: Zhu JM, Charlesworth CJ, Polsky D, McConnell KJ. Phantom Networks: Discrepancies Between Reported And Realized Mental Health Care Access In Oregon Medicaid. Health Aff (Millwood). 2022 Jul;41(7):1013–1022. doi: 10.1377/hlthaff.2022.00052. PMID: 35787079; PMCID: PMC9876384. Available from: <https://pmc.ncbi.nlm.nih.gov/articles/PMC9876384/>.

⁴ Medicare Provider and Supplier Taxonomy Crosswalk. CMS: Nov 2025. Available from: <https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/medicare-provider-and-supplier-taxonomy-crosswalk>.

¹ Office of Evaluation and Inspections. Many Medicare Advantage and Medicaid Managed Care Plans Have Limited Behavioral Health Provider Networks and Inactive Providers. Office of Inspector General: October 2025. Available from: <https://oig.hhs.gov/documents/evaluation/11233/OEI-02-23-00540.pdf>.

² Office of Evaluation and Inspections. Many Medicare Advantage and Medicaid Managed Care

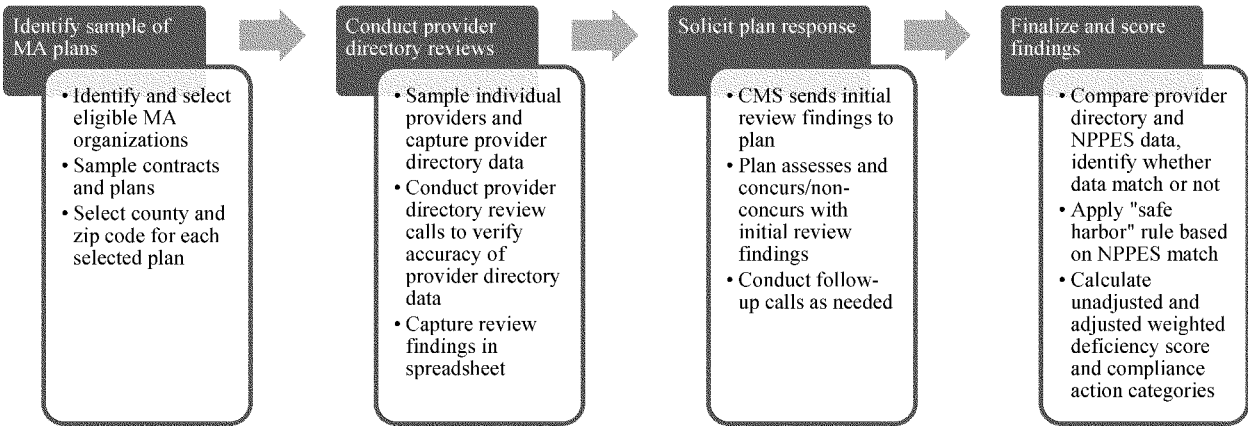
accuracy scores and the MA network adequacy requirements have a specific different purpose that cannot be directly applied to the sampling frame. Although CMS did not propose this alternative, CMS is still actively considering this approach and seeks comment.

CMS is also considering some additional provider specialty types with high provider directory inaccuracy rates for inclusion at new proposed § 422.123(d)(2)(ii). CMS has previously conducted reviews of MA organizations' online provider directories. CMS conducted its most recent three rounds of reviews between June 2022 and June 2024. While CMS has published a report for the MA online provider directory reviews in the past, CMS did not publish a report for these most recent reviews.⁵ Similar to past reviews, the goal of these recent reviews was to gain a better understanding of MA provider directory accuracy, identify best practices for maintaining accurate provider directories, and, through appropriate compliance actions, drive industry improvement in providing more accurate provider directories. During the reviews conducted between June 2022 and June 2024, CMS

examined the accuracy of online provider directories for 142 MA organizations that offered at least one eligible MA–PD plan.⁶ During each review round, CMS randomly sampled one contract offered by each MA organization, then randomly sampled an eligible plan from each contract. CMS designated some contracts to be “rural” and some to be “urban” to ensure a mix of urban and rural service areas for the eligible plan selected for each contract. If the eligible plan for a contract that was designated as “rural” only served urban counties, then the contract was re-designated as “urban” and another contract/eligible plan was designated as “rural.” Because many MA online provider directories require users to enter a zip code to search for providers, CMS selected a county within each plan’s service area and then selected a zip code within the search county to use as the search zip code. During each review round, CMS assessed the accuracy of the provider directory listings of between 80 and 100 providers from each selected plan. In rounds one and two, CMS assessed the accuracy of 20 providers of each of the following four provider specialty types: (1)

primary care providers (PCPs), (2) cardiologists, (3) oncologists, and (4) ophthalmologists.⁷ During round three, CMS added reviews of provider directory listings for a fifth provider specialty type (mental health providers), reviewing 20 mental health providers from each plan.⁸ CMS reviewed approximately one-third of eligible MA organizations during each review round. CMS found that out of the 11,360 providers and 18,852 locations reviewed across all three rounds, 44.29 percent of the location listings in the online provider directories contained at least one inaccuracy (“deficiency”), such as: The provider did not see patients at the location listed, the phone number was incorrect, the address was incorrect, the provider did not accept the plan at the location, or the provider’s information could not be verified. Figure II.B.1 provides a high-level overview of the MA online provider directory review methodology. Reviewers captured provider directory data for sampled providers, placed calls to provider offices to verify the accuracy of the online provider directory data, and recorded findings in an MA organization-specific spreadsheet.

FIGURE II.B.1: MA ONLINE PROVIDER DIRECTORY REVIEW METHODOLOGY OVERVIEW



CMS made minor changes to the review methodology between the review

rounds, incorporating lessons learned and refining the review approach. In

round three, CMS incorporated two new final deficiencies: “Provider should not

⁵For example, CMS published this Online Provider Directory Review Report in 2018: https://www.cms.gov/medicare/health-plans/managedcare/marketing/downloads/provider_directory_review_industry_report_round_3_11-28-2018.pdf.

⁶The population from which plans were selected was the universe of all MA and PDP plans with enrollment at the time the reviews were conducted across the United States and its territories. The sample excluded certain types of plans either because they were not MA plans or because the

plan type could not adequately be compared to most MA PDPs. Excluded types of plans were: private fee-for-service plans, MA-only plans, employer group waiver plans, Medicare Part D plans, medical savings account plans, 1876 cost plans, health care prepayment plans—1833 cost plans, PACE plans, special needs plans, and financial alignment demonstration plans—Medicare-Medicaid Plans.

⁷In some cases, a plan’s network did not contain enough of one provider type to meet the sample size

of 20. In these cases, CMS sampled additional “supplemental” PCPs from the plan to meet the sample size.

⁸The mental health providers sampled included the following types: Clinical Psychologist, Clinical Social Worker, Licensed Clinical Social Worker, Licensed Professional Counselor, Psychiatry, Psychologist, and Certified Alcohol and Drug Counselor I, II, or III. Nurse practitioners were excluded.

be listed in the directory at this location—information could not be verified” and “Provider should not be listed in the directory at this location—does not accept plan” to capture more nuance about why a provider should not

be listed at a location in the directory. Additionally, in round three, when reviewers found providers who only worked in a telehealth capacity, CMS assigned the provider directory record the deficiency of “Address needs to be

updated” with a note indicating that the provider only sees patients in a telehealth capacity.

Table II.B.1 provides the review counts of individual providers and locations by provider type.

**TABLE II.B.1: PROVIDER TYPES AND LOCATIONS REVIEWED FROM JUNE 2022
– JUNE 2024**

Provider Specialty Type	Round 1		Round 2		Round 3		All	
	Providers Reviewed	Locations Reviewed	Providers Reviewed	Locations Reviewed	Providers Reviewed	Locations Reviewed	Providers Reviewed	Locations Reviewed
PCPs	1,087	1,482	1,070	1,417	887	1,184	3,044	4,083
Cardiologists	989	1,919	970	1,651	839	1,539	2,798	5,109
Oncologists	946	1,712	965	1,556	814	1,431	2,725	4,699
Ophthalmologists	978	1,923	995	1,655	820	1,383	2,793	4,961
Total	4,000	7,036	4,000	6,279	3,360	5,537	11,360	18,852

At the conclusion of the June 2022 through June 2024 review process, CMS analyzed the data from all three review rounds to highlight notable findings on

MA organization performance. The data is summarized for each round and for all three rounds together. Table II.B.2 lists deficiency counts and rates for all

three rounds, broken out by location and provider specialty type.

TABLE II.B.2: DEFICIENCY COUNTS AND RATES BY LOCATION AND PROVIDER TYPE

Provider Specialty Type	Round 1		Round 2		Round 3		All	
	Deficient Locations	Deficiency Rate	Deficient Locations	Deficiency Rate	Deficient Locations	Deficiency Rate	Deficient Locations	Deficiency Rate
PCPs	635	42.85%	697	49.19%	535	45.19%	1,867	45.73%
Cardiologists	873	45.49%	785	47.55%	777	50.49%	2,435	47.66%
Oncologists	777	45.39%	649	41.71%	720	50.31%	2,146	45.67%
Ophthalmologists	810	42.12%	574	34.68%	518	37.45%	1,902	38.34%
Total	3,095	43.99%	2,705	43.08%	2,550	46.05%	8,350	44.29%

Given that this online provider directory review data is data that CMS has available, CMS considered proposing to use this data to identify provider specialty types with high provider directory inaccuracy rates. CMS considered including provider specialty types with a deficiency rate of 45 percent or above across all three rounds of review, which would include PCPs, cardiologists, and oncologists. CMS recognizes that there are limitations to using this data for this purpose, as it was originally gathered for a different purpose. This data is also limited because it only includes four provider specialty types that were incorporated in all three rounds of review, with one added provider specialty type incorporated in only the third (and last) round of review. Although CMS did not propose to include PCPs, cardiologists, and oncologists as provider specialty types with high provider directory inaccuracy rates, they remain under active consideration by CMS. CMS seeks

comments on the inclusion of these provider specialty types as provider specialty types with high provider directory inaccuracy rates. CMS also seeks comments on whether there are any other provider specialty types that should be considered provider specialty types with high provider directory inaccuracy rates. If CMS were to include any other provider specialty types as provider specialty types with high provider directory inaccuracy rates, CMS would follow a similar process as described with the proposed inclusion of mental health or substance use disorder treatment provider specialty types, meaning CMS would review the available Medicare specialty codes and NUCC taxonomy codes, propose the codes in annual technical guidance for comment, and then issue guidance with the final list of codes taking into account commenters’ feedback. If commenters on this proposed rule recommend that CMS identify any other provider specialty types in regulation, then CMS encourages commenters to

include in their comments what Medicare specialty codes and/or NUCC taxonomy codes would be relevant for CMS to propose in annual technical guidance.

At this time, this is the information available to CMS to determine provider specialty types with high provider directory inaccuracy rates, however, as described in section II.B.6. of this proposed rule, CMS is considering collecting data from MA organizations in addition to the accuracy score, such as provider specialty type response rates by verification method or other sampling data by provider specialty type, which could inform future rulemaking regarding determinations of provider specialty types with high provider directory inaccuracy rates. This data could be supplemented with other external research. CMS seeks comments on other methods and other potential sources of data that CMS could use to determine provider specialty types with high provider inaccuracy rates.

At new proposed § 422.123(d)(2)(iii), CMS proposes to require that MA organizations identify the sampling frame as consisting of provider records in the provider directory with a unique provider, address, and phone number. Thus, when considering the universe of possible provider records that may be chosen for the sample, each provider record that could be selected in that universe would need to be a unique provider at a specific address and phone number. This means that, for example, a provider could be included in the sample at one address but not at another address. Similarly, if there is a case where a provider has two different phone numbers at the same address, then one provider/address/phone combination could be selected to be in the sample, but not the other. CMS proposes this approach for the sampling frame because CMS is aiming to ensure that a provider record constitutes a single, unique listing in the provider directory, and CMS believes that using the unique provider, address, and phone number constitutes a single, unique listing. When determining a unique provider for their sampling frame, CMS recommends that MA organizations use the provider's National Provider Identifier (NPI) because the NPI uniquely identifies the provider. CMS notes that a notice that the provider information may be outdated, per the proposed requirement at new proposed § 422.123(b)(3) as discussed in section II.B.2. of this proposed rule, does not mean that records associated with the provider would be excluded for purposes of sampling. A provider with such a notice would still be considered part of the sampling frame. CMS seeks comments on this proposal.

CMS is also considering identifying the sampling frame for MA organizations as consisting of provider records that contain a unique provider and address. CMS identified a drawback to this approach because there may be cases where a provider has the same address but different phone numbers, potentially creating confusion for MA organizations when they are determining their sampling frame. CMS seeks comments on whether the proposed identification of the sampling frame as a provider record in the provider directory with a unique provider, address, and phone number is appropriate or whether only a unique provider and address would be needed to identify a unique provider record. CMS also seeks comments on other data elements that may be necessary to identify a unique provider record for the sampling frame.

CMS is proposing that MA organizations would create a sample set for purposes of the proposed accuracy analysis methodology as described in new proposed § 422.123(d)(2)(iv). At new proposed § 422.123(d)(2)(iv)(A), CMS proposes to require that MA organizations use a simple random sample with 65 percent of the sample made up of any providers in the provider directory except those with provider specialty types with high provider directory inaccuracy rates identified in § 422.123(d)(2)(ii), and 35 percent of the sample made up of providers with provider specialty types with high provider directory inaccuracy rates identified in § 422.123(d)(2)(ii). In its current proposal, CMS proposes only one provider specialty type with high provider directory inaccuracy rates at § 422.123(d)(2)(ii)(A), the provider specialty type of mental health or substance use disorder treatment. Therefore, if finalized as proposed, the 35 percent portion of the sample would be made up of only providers in the mental health or substance use disorder treatment provider specialty type. If there are more provider specialty types that CMS incorporates as provider specialty types with high provider directory inaccuracy rates, then CMS would include in regulation the portion of the 35 percent of the sample that should be made up of each provider specialty type. If this were to occur, CMS anticipates an even split in the sample amongst provider specialty types with high provider directory inaccuracy rates but will consider whether certain provider specialty types should make up more of the sample than others. CMS seeks comments on the proposed sampling methodology at new proposed § 422.123(d)(2)(iv). In addition, CMS intends to release annual technical guidance with additional information regarding its sampling methodology.

CMS is also considering stratified sampling based on county type as a way to create a sample set. CMS is considering assigning counties into two groups, one containing Large Metro, Metro, and Micro counties and a second group with Rural counties and Counties with Extreme Access Considerations (CEAC). CMS is considering defining a proportion of records that should come from each grouping. CMS is also considering using a three-group stratification of Large Metro and Metro counties making up one group, Micro counties making up a second group, and Rural and CEAC counties making up a third group, or having all five county types representing separate strata. CMS

understands that the dynamics associated with each county type are different, but sampling this way may also introduce complications. For example, a specific provider may serve MA plan enrollees in both a Rural and Micro county, introducing additional steps into the sampling methodology. Due to CMS concerns about the possible additional layer of complexity and the consideration of administrative burden on MA organizations and providers, CMS has not proposed stratified sampling based on county type at this time but CMS is still actively considering this approach. CMS seeks comments about whether CMS should include any of these alternative approaches in the sampling methodology or consider other alternative approaches.

In the proposed sampling methodology described in § 422.123(d)(2), CMS is also considering specifying a number or percentage of records that must be included in the sample. CMS is concerned with ensuring that conducting accuracy analysis on the sample is not overly burdensome (that is., that the sample is not too large) but also that there are enough records in the sample to ensure that the accuracy scores calculated are meaningful (that is, that the sample is not too small). CMS seeks comments on the number or percentage of records that should be included in the sample.

CMS is considering whether the proposed sampling methodology described in § 422.123(d)(2) should specify a maximum number or percentage of records that may be incorporated in the sample. CMS understands that provider networks for specified MA plans vary considerably depending on the size of the MA organization, the number of plans offered, and where an MA organization operates, among other considerations. Conducting an accuracy analysis may be more burdensome for some MA organizations than for other MA organizations, some may prefer to use a larger sample size, and some may prefer to use a smaller sample size. MA organizations that are able to conduct provider directory accuracy analysis using a larger sample size may find that they can increase their accuracy score this way relative to an MA organization who prefers to use a smaller sample size, or they may find that using a larger sample size decreases their score while increasing the associated burden. Large differences in the sample sizes used by MA organizations may affect the comparability of the resulting accuracy scores. CMS is seeking comments about whether CMS should have a maximum

number or percentage of records that may be incorporated in the sample and what that maximum number or percentage should be. Specifically, CMS is seeking comments on such issues as, whether there should be different considerations based on the size of MA organizations or in which types of counties MA organizations operate (Large Metro, Metro, Micro, Rural, CEAC); whether there are other differences between MA organizations that CMS should consider when determining the maximum number or percentage of records in the sample; and how CMS can help to ensure that there is a level playing field among all MA organizations. While CMS has not proposed a specific value in regulation at this time, CMS seeks comments on what values for a maximum number or percentage may be appropriate as part of the sampling methodology CMS intends to adopt, as well as comments on the considerations discussed previously.

In addition, CMS is considering whether the proposed sampling methodology described in § 422.123(d)(2) should specify a minimum number or percentage of records both for each provider specialty type with high provider directory inaccuracy rates at § 422.123(d)(2)(ii) and for an overall minimum number or percentage of records that must be in the sample. As noted earlier, CMS is interested in balancing the need to ensure that the sample is large enough to be sufficient to calculate the accuracy scores but also not so large as to be overly burdensome for MA organizations. Some smaller MA organizations or MA organizations with plans in rural areas may have fewer providers in their networks than other MA organizations. Considering both goals of having enough of a sample for a meaningful accuracy score calculation and minimizing administrative burden on MA organizations and providers, CMS seeks comments on what the minimum number or percentage of providers for each provider specialty type with high provider directory inaccuracy rates should be. While CMS has not proposed a specific value in regulation at this time, CMS seeks comments on what values for a minimum number or percentage may be appropriate as part of the sampling methodology CMS intends to adopt, as well as comments on the considerations discussed as part of the sampling methodology CMS intends to adopt.

Since the provider directory accuracy score must be reported for each specified MA plan, as discussed in section II.B.6. of this proposed rule, CMS's understanding is that the sample

that supports the accuracy score will also need to be drawn at the plan level. However, to limit the burden on both MA organizations and providers, CMS intends to require that MA organizations consolidate their samples across the MA organization. For example, if a provider appears in multiple samples because they are contracted to participate with multiple MA plans, and the MA organization chooses the verification method of email (as described later), then using that verification method one time would be sufficient for each sample the provider appears in, and there would be no need to email the provider multiple times.

As part of the annual provider directory accuracy analysis and sampling methodology that CMS proposes to implement in § 422.123(d)(1) and (d)(2), CMS is considering also setting parameters governing when MA organizations must draw samples for purposes of the proposed annual accuracy analysis. CMS is considering the possibility that the MA organizations would be required to draw samples on a specified date, or dates, each year. This would ensure that results are directly comparable across plans, would reduce the risk of gaming, and would simplify the ability of beneficiaries to compare provider directory accuracy across plans. CMS also recognizes that there may be certain disadvantages to this approach, including operational constraints related to a specific date, the potential for MA organizations to focus on accuracy efforts for a known date rather than maintaining accuracy on an ongoing basis, and that such an approach limits flexibility for MA organizations. Alternatively, CMS could allow MA organizations to choose the date on which they draw their samples for their specified MA plans. This approach would provide operational flexibility and may reduce the administrative burden associated with sampling, but it would reduce the comparability across plans, increase the risk of gaming, and may increase oversight complexity for CMS. CMS is also considering some hybrid approaches, such as defining a window (for example, one quarter) and randomly assigning a date to an MA organization within that quarter or announcing the date on which the sample should be pulled with minimal advance notice. While CMS has not proposed a specific timeframe for the sample drawing in regulation at this time, CMS seeks comments on these considerations as part of the annual provider directory

accuracy analysis and sampling methodology that CMS intends to adopt.

In summary, CMS is proposing to codify the provider directory accuracy analysis requirement at new proposed § 422.123(d)(1) and the sampling methodology for such analysis at new proposed § 422.123(d)(2). CMS solicits comments on these proposed changes.

5. Provider Directory Accuracy Score and Scoring Methodology (§ 422.123(d)(3) and (4))

Section 1857(e)(6)(B)(i) of the Act requires that the Secretary shall specify plan verification methods, such as using telephonic verification or other approaches using data sources maintained by an MA organization or using publicly available data sets, that MA organizations may use for estimating accuracy scores of the provider directory information of specified MA plans offered by such organizations.

To implement these statutory requirements, first CMS proposes to require that MA organizations must estimate an accuracy score reflecting the accuracy of the provider directory information. Furthermore, CMS proposes that the accuracy score must be: (1) estimated using the verification methods specified in new proposed § 422.123(b)(2) for specified provider directory elements, (2) based on the verification results for the random sample specified in new proposed § 422.123(d)(2)(i) and (d)(2)(ii) using the sampling methodology specified in new proposed § 422.123(d)(2)(iii), and (3) represented in the form of a letter grade. CMS proposes to add these provider directory accuracy score requirements at new proposed § 422.123(d)(3).

At new proposed § 422.123(d)(3)(i), CMS proposes to limit what verification method(s) may be used by MA organizations to estimate the provider directory accuracy score, such that certain provider directory elements may only be verified using certain verification methods. CMS notes that this proposed limitation of verification method(s) for certain provider directory elements only applies to MA organizations' verification methods for purposes of estimating the accuracy score at new proposed § 422.123(d)(3), not to the verification methods for the 90-day/12-month verification at new proposed § 422.123(b)(2). At new proposed § 422.123(d)(3)(i)(A), CMS proposes to limit the verification method "internal plan information" to be used only to confirm network participation status (that is, that the provider is currently contracted and participating in that MA plan's provider

network) and specialty because it is possible that internal plan information may be dated and contain information about a provider that is not current (for example, an old address). At new proposed § 422.123(d)(3)(i)(B) and (d)(3)(i)(C), CMS proposes to limit the use of the methods “telephonic verification” and “email verification” to the following provider directory elements: specialty; contact information; primary office or facility address(es); whether the provider is accepting new patients; accommodations for people with disabilities; and telehealth capabilities. CMS believes that direct interaction with the provider through telephone or email communication is the most effective way to verify the accuracy of these provider directory elements. CMS has not proposed using telephone or email communication to verify network participation status because telephone and email communication are two verification methods that may cause a higher burden on providers, so considering that network participation can be verified using other verification methods, CMS has not proposed to include that here. Further, CMS proposes that the verification method of provider attestations at new proposed § 422.123(d)(3)(i)(D) would not be limited to any specified provider directory elements. That is, MA organizations would be permitted to use provider attestations to verify any provider directory element. Lastly, CMS proposes that the verification method of claims data at new proposed § 422.123(d)(3)(i)(E) may be used to confirm the provider directory elements of network participation status and specialty. At this time, CMS has not proposed any provider directory elements that can be verified for the purposes of the accuracy score with the verification method “data sources maintained by CMS.” CMS may revisit this verification method with the development of the NPD and may

incorporate the NPD as a verification method that may be used for one or more provider directory elements. CMS seeks comments on, for purposes of the accuracy score, whether there are data sources maintained by CMS that commenters recommend for use as reliable sources for any of the provider directory data elements. Finally, if CMS specifies other verification methods in technical guidance, as noted in new proposed § 422.123(b)(2)(vii), then CMS will identify which provider directory elements the verification method may be used for, for purposes of estimating the accuracy score at new proposed § 422.123(d)(3).

CMS understands that certain verification methods depend on a response from a provider, and a provider may not respond. If a provider does not respond to one verification method, another verification method may be used, but it is possible that an MA organization could exhaust the possible verification methods for a specific provider directory data element for their specified MA plan. As part of the sampling methodology that CMS proposes to implement in § 422.123(d)(2), CMS may implement a process for an MA organization to move on to another permitted verification method. For example, a possibility may be that if a provider did not respond within 7 business days, including at least one reminder, then the MA organization may consider that verification method exhausted and move on to another. In the event that all possible verification methods are exhausted for a particular record, CMS seeks comments on whether an MA organization should incorporate a new record into its sample to replace the non-response. The ability to add additional records into the sample if there are non-responses would prevent the sample from becoming so small as to be insufficiently comparable to the samples of other specified MA plans. However, MA organizations may also

choose to oversample in order to ensure that sufficient providers respond, which may increase the administrative burden on MA organizations and providers. CMS also understands that some provider specialty types may be more difficult to receive responses from than others, and therefore seeks comments on whether there should be requirements to fill the sample with the same type of provider as a non-responding provider. Given the possibility of non-response, CMS is also considering implementing a minimum response rate that each MA organization must meet for a specified MA plan and requests comments on what that minimum response rate should be. CMS also seeks comments on the provider non-responses and how they should be considered in the sampling methodology and verification methods.

The next provision of the REAL Health Providers Act that CMS is implementing is the provider directory accuracy scoring methodology. Section 1857(e)(6)(B)(ii) of the Act states that with respect to each verification method, the Secretary shall specify a methodology for MA organizations to use in estimating such accuracy scores, and that each such methodology shall take into account the administrative burden on plans and providers and the relative importance of certain provider directory information on enrollee ability to access care.

To describe the proposed provider directory accuracy scoring methodology, CMS will use an example throughout this section. This example is simplified for purposes of illustrating the scoring methodology. For each element in the proposed definition of provider directory information, Table II.B.3 indicates the results of the verification process the MA organization for MA plan Y would follow pursuant to the proposed sampling and verification methodology described in new proposed § 422.123(d)(2) and (d)(3):

TABLE II.B.3: EXAMPLE OF SAMPLE PROVIDER DIRECTORY ACCURACY DATA

Provider Directory Element	Health Hospital	Jane Doe <i>Specialty A</i>	Jack Doe <i>Specialty A</i>	Jacklyn Doe <i>Specialty B</i>	Jeffrey Doe <i>Specialty B</i>	John Doe <i>Specialty C</i>
Network participation status	Accurate	Accurate	Not Accurate (that is, provider in directory but not in network)	Accurate	Accurate	Accurate
Specialty	Accurate	Accurate	Accurate	Accurate	Not Accurate	Accurate
Contact information, including telephone number(s)	Accurate	Not Accurate	Not Accurate	Accurate	Accurate	Not Accurate
Primary office or facility address(es) where covered items or services are furnished	Accurate	Accurate	Accurate	Not Accurate	Not Accurate	Accurate
Whether the provider is accepting new patients	Accurate	Not Accurate	Not Accurate	Accurate	Accurate	Accurate
Accommodations for people with disabilities	Accurate	Accurate	Accurate	Accurate	Accurate	Not Accurate
Telehealth capabilities	Accurate	Accurate	Accurate	Accurate	Not Accurate	Accurate

CMS proposes using a binary system of “accurate” and “not accurate” for each provider directory data element. Some of the data elements consist of multiple parts that make up the data element. For example, a provider’s address may consist of a first address line, a second address line, a city, a state, and a zip code. A provider directory data element should only be considered “accurate” if all of the parts of that provider directory data element are correct. For example, if a provider’s address has the correct first address line, city, and state, but wrong second address line and zip code, then the address would be considered “not accurate.” CMS notes that a difference in the address such as the use of the comment abbreviation “st” instead of “street” or “ct” instead of “court” would not prevent an address from being considered accurate as such differences would be considered non-material. CMS proposes this method because the aim of the accuracy score analysis is to see how correct each of the various elements are in the provider directory, and this means that each of

the multiple parts that make up the data element must be correct for the whole data element to be correct.

CMS is considering offering a “partial” score if at least half of the multiple parts that make up the provider directory data element are correct. In that methodology, a score of “not accurate” would be 0, and a score of “accurate” would be 1, and if it was partially correct, the score would be “0.5.” In the address example mentioned previously, since 3 of the 5 parts of the data element were correct, that record would receive a score of 0.5 rather than 0. Some drawbacks of this approach are that it may unnecessarily complicate the scoring methodology and perpetuate inaccurate provider directory information. CMS did not propose this methodology but CMS is still actively considering this approach. CMS seeks comments on whether a score should be included for partial accuracy of any of the provider directory data elements.

CMS is also considering a confidence scoring approach to determine the accuracy or inaccuracy of a given provider directory data element. Using a

confidence scoring approach, a score of “accurate” or 1 would be assigned to a provider directory data element if such data element matched least two or more verification methods, a score of “partially accurate” or 0.5 would be assigned if a provider directory data element matched at least one verification method, and a score of “inaccurate” or 0 would be assigned if a provider directory data element did not match any attempted verification methods. A concern that CMS identified is that this confidence scoring approach would be more burdensome because it would require validation against multiple sources. CMS has not proposed this methodology, but CMS is still actively considering this approach. CMS seeks comments on whether a confidence scoring approach should be used.

CMS is proposing a weighted provider directory accuracy scoring methodology at new proposed § 422.123(d)(4). CMS proposes to use the weights in Table II.B.4 for each element under consideration.

TABLE II.B.4: PROPOSED WEIGHTS BY PROVIDER DIRECTORY ELEMENT

Provider Directory Element	Weight
Network participation status	40%
Specialty	10%
Contact information, including telephone number(s)	20%
Primary office or facility address(es) where covered items or services are furnished	20%
Whether the provider is accepting new patients	3%
Accommodations for people with disabilities	3.5%
Telehealth capabilities	3.5%

CMS notes that “provider name,” “common ownership or control disclosure,” and “cultural and linguistic capabilities” are not elements incorporated into the proposed provider directory accuracy scoring methodology. Thus, even though these three provider directory elements are part of the definition of provider directory information as defined in proposed § 422.2, they would not count towards the accuracy score. CMS has not proposed that these elements be part of the accuracy scoring methodology. CMS did not propose to include “provider name” in the proposed provider directory accuracy scoring methodology because CMS believes this element is likely to be correct and is therefore of lower priority to incorporate into the scoring methodology. CMS did not propose to include “common ownership or control disclosure” in the accuracy score methodology because CMS has limited experience with this as a provider directory element and therefore a higher level of uncertainty regarding the burden on MA organizations and providers associated with collecting and maintaining this information. Lastly, CMS did not propose to include “cultural and linguistic capabilities” in the accuracy scoring methodology to reduce burden. This provider directory element may be difficult to consistently evaluate using the binary scoring methodology that CMS proposes. CMS believes that not proposing the inclusion of an element that is likely to contain information of a more varied and open-ended nature may limit some burden associated with the scoring methodology on MA organizations and providers. CMS seeks comments on whether “provider name,” “common ownership or control disclosure,” or “cultural and linguistic capabilities” should be incorporated into the accuracy scoring methodology, or if CMS should request that MA organizations collect data on the accuracy of these elements to inform potential future inclusion of these elements in the accuracy scoring

methodology. CMS may consider whether to incorporate this information into future accuracy reporting after evaluating comments and experience with implementation.

CMS is proposing these weights to emphasize the accuracy of certain elements in the provider directory to focus the attention of MA organizations on specific elements most significant to ensuring beneficiaries can access care. CMS proposes a weight of 40 percent for network participation status (that is, per proposed § 422.2, that the provider listed in the directory is a provider with which the MA organization offering the MA plan has an agreement for furnishing items and services covered under such plan) because this is the most foundational piece of information in a provider directory. Beneficiaries expect that the providers listed in the directory are in the MA plan’s network, and, as such, beneficiaries expect to be able to access care from these in-network providers at in-network cost sharing. An error in network participation status can lead a beneficiary to unknowingly receive out-of-network care, which may result in higher costs and undermine continuity of care.

CMS proposes a weight of 20 percent for both contact information and primary office or facility address. Beneficiaries and caregivers may frequently rely on contact information from the directory to call the provider to schedule an appointment, and an incorrect phone number creates an immediate barrier for a beneficiary to access care. Beneficiaries and caregivers also need an accurate primary office or facility address to physically reach the provider, so an incorrect address would create an immediate barrier to receiving care. Also, beneficiaries may choose which provider to schedule an appointment with based on the proximity of the address to their home or other places they frequently visit. If the address information is inaccurate, then a beneficiary may inadvertently call or schedule an appointment with a

provider at an address that they cannot easily access.

CMS proposes a weight of 10 percent for the provider’s specialty. Accurate specialty information helps beneficiaries identify the provider for the beneficiary’s particular health care needs. Inaccurate specialty information may lead the beneficiary to contact several providers before one with the correct specialty can be identified, which may slow the beneficiary’s access to needed care.

CMS proposes a weight of 3.5 percent whether the provider has accommodations for people with disabilities and has telehealth capabilities. These elements provide important information to beneficiaries as they seek access to care. Beneficiaries with disabilities may need certain accommodations, and knowledge of which providers can accommodate them is integral to their decision making. Knowledge of a provider’s telehealth capabilities allows beneficiaries to choose a provider that offers the option for telehealth appointments. While these two elements with the proposed weight of 3.5 percent are meaningful and important for beneficiaries to access needed care, the potential for harm if any of these elements are incorrect is more limited because beneficiaries can still identify and contact providers even if these elements are inaccurate in the provider directory. Also, the accommodations for people with disabilities provider directory element affects a subset of the overall beneficiary population, which justifies a lower proposed weight relative to the universally applicable elements.

CMS proposes a weight of 3 percent for whether the provider is accepting new patients. This element shares a lot of similarities with whether the provider has accommodations for people with disabilities and has telehealth capabilities discussed previously. This is also an element which provides important information to beneficiaries as they seek access to care. Knowing whether a provider is

accepting new patients may help beneficiaries identify providers that may have available appointments. In addition, while this element is also meaningful and important for beneficiaries to access needed care, the potential for harm if this element is incorrect is more limited because beneficiaries can still identify and contact providers even if this element is inaccurate in the provider directory. CMS proposes a weight of 3 percent rather than 3.5 percent proposed for whether the provider has accommodations for people with disabilities and has telehealth capabilities because of the three elements, CMS believes whether the provider is accepting new patients may be an element that could change more frequently than other elements and therefore may be a challenging provider directory element for MA organizations to collect and maintain. Recognizing the possible additional burden associated with collecting and maintaining this element for both MA organizations and providers, CMS proposes a slightly lower weight than the other two similar elements. Further, as a practical matter,

CMS also wanted to ensure the proposed weights added up to 100 percent, and the most straightforward way to do that was to use weights of 3.5 percent for two elements and 3 percent for one element.

Given these weights, CMS's proposed provider directory accuracy scoring methodology (also described in Table II.B.5) is that first, the MA organization would need to sum the number of accurate records for each element across all providers in the specified MA plan's sample and then divide the number of accurate records for each element by the number of providers in the sample to determine the Accuracy Percentage per Element. Then, CMS proposes that the MA organization would need to multiply the Accuracy Percentage by Element by the Element Weight in Table II.B.5, to determine the Weighted Score per Element. In the example earlier, the accuracy percentage for the element "Network Participation Status" is 5 divided by 6, or $5/6 = 0.833333$ and then the weighted score for that element would be

0.833333 multiplied by 0.4, or $0.833333 \times 0.4 = .333333$.

To determine the Final Composite Score, CMS proposes that the MA organization would need to sum the Weighted Score per Element. Then, CMS proposes that the MA organization would need to multiply the Final Composite Score by 100 to convert to a percentage, then round to the nearest whole number to determine the Rounded Composite Score. As a result, CMS proposes that, to determine the final Provider Directory Accuracy Score, the MA organization would need to convert the Rounded Composite Score to the appropriate letter grade. CMS proposes that 90 percent to 100 percent would be equivalent to a grade of "A," 80 percent to 89 percent would be equivalent to a grade of "B," 70 percent to 79 percent would be equivalent to a grade of "C," 60 percent to 69 percent would be equivalent to a grade of "D," 50 percent to 59 percent would be equivalent to a grade of "E," and 49 percent and below would be equivalent to a grade of "F." Table II.B.5 illustrates this calculation for MA plan Y's scores in the example.

TABLE II.B.5: METHODOLOGY CALCULATION

Provider Directory Element	Number of Accurate Records	Number of Providers in Sample	Accuracy Percentage Per Element	Element Weight	Weighted Score Per Element
Network participation status	5	6	0.833333	40%	0.333333
Specialty	5	6	0.833333	10%	0.083333
Contact information, including telephone number(s)	3	6	0.5	20%	0.1
Primary office or facility address(es) where covered items or services are furnished	4	6	0.666667	20%	0.133333
Whether the provider is accepting new patients	4	6	0.666667	3%	0.02
Accommodations for people with disabilities	5	6	0.833333	3.5%	0.029167
Telehealth capabilities	5	6	0.833333	3.5%	0.029167
Final Composite Score					0.728333
Rounded Composite Score					73%
Provider Directory Accuracy Score					"C"

In this example, for MA plan Y, the accuracy score would be a "C" because the Rounded Composite Score is 73 percent. Note that while Table II.B.5 only includes 6 decimal places, CMS proposes that MA organizations should not round to the nearest whole number until they get to the Final Composite Score calculation. That calculation should then be rounded to the nearest whole number and be represented in the

form of a percentage as the Rounded Composite Score. CMS is proposing these requirements for the provider directory accuracy scoring methodology in new proposed § 422.123(d)(4).

In developing this proposal, CMS considered a scoring methodology approach that incorporated the proposed verification requirements, described at new proposed § 422.123(b), into the accuracy score. Table II.B.6

shows the sample data for one of the example providers, Jane Doe, with accuracy records from both when the sample was drawn and during the most recent 90-day verification that the MA organization conducted. As seen in Table II.B.6, the results from the accuracy of the provider directory information may be different on the date that the sample is drawn as compared to the date of the 90-day verification.

TABLE II.B.6: EXAMPLE OF SAMPLE AND VERIFICATION ACCURACY DATA

Provider Directory Element	Jane Doe (Accuracy record when the sample was drawn) <i>Specialty A</i>	Jane Doe (Accuracy record during most recent 90-day verification) <i>Specialty A</i>
Network participation status	Accurate	Accurate
Specialty	Accurate	Accurate
Contact information, including telephone number(s)	Accurate	Not Accurate
Primary office or facility address(es) where covered items or services are furnished	Accurate	Accurate
Whether the provider is accepting new patients	Accurate	Not Accurate
Accommodations for people with disabilities	Accurate	Accurate
Telehealth capabilities	Accurate	Accurate

CMS is considering a methodology in which the MA organization use both records of provider directory accuracy data when they develop the accuracy score. This may provide additional incentives for MA organizations to ensure their verification activities are thorough and also not unduly penalize MA organizations if through most of the year the provider directory information is correct but happened to be incorrect when the sample was drawn. A possible drawback for this approach is that MA organizations could choose the exact timing that they conduct their verification as long as it is consistent with CMS requirements at new proposed § 422.123(b), which may introduce opportunities for gaming, and the resulting accuracy scores may also be less of a direct “apples-to-apples” comparison between specified MA plans given these differences. CMS considered several different ways to incorporate the verification results into the accuracy score methodology. For example, CMS considered incorporating the most recent verification for the provider and also considered incorporating the results from all of the 90-day and 12-month verifications that the MA organization completed. Additionally, CMS considered whether the verification results should be weighed equally with the sample, whether the sample should be weighed more than the verification results, or whether the verification results should be weighed more than the sample. CMS further considered whether specific verification methods would have to be used if the verification results were incorporated into the provider directory accuracy score. For example, CMS considered requiring that only verification results that used the same verification method as the sample could be included. CMS has not proposed incorporating the verification results into the accuracy score at this time

because a more complex scoring methodology may increase the burden on MA organizations and providers, but CMS is still actively considering these approaches and interested in comments on whether CMS should consider an accuracy scoring methodology that incorporates the verification results.

CMS is also considering whether certain provider specialty types with high provider directory inaccuracy rates should be weighed in the accuracy score more so than other provider specialty types and whether certain provider specialty types, regardless of whether it is considered a provider specialty type with high provider directory inaccuracy rates, should be weighed in the accuracy score more so than other provider specialty types. A drawback of either of these approaches is that they would likely add additional complexity into the provider directory accuracy scoring methodology. CMS has not proposed either of these approaches but is still considering them and seeks comments on whether accuracy scores should be calculated differently for provider specialty types with high provider directory inaccuracy rates or if scores for certain provider specialty types should be calculated differently regardless of whether it is considered a provider specialty type with high provider directory inaccuracy rates.

CMS is further considering whether geographical considerations should be part of the scoring methodology. CMS is considering whether records in the sample with an address in a rural or CEAC county should have different weights associated with the provider directory data elements or whether some provider directory data elements should not be included in the scoring methodology for records in the sample with an address in a rural or CEAC county. CMS is also considering whether specified MA plans with 75 percent or more of their service area in

rural and CEAC counties should have a different scoring methodology than other plans. CMS recognizes that a drawback of this approach may be that it represents less of a direct “apples-to-apples” comparison among specified MA plans and also that it may add additional complexity to the scoring methodology. CMS has not proposed different scoring methodologies based on geographic considerations but is still actively considering this approach. CMS seeks comments on whether different scoring methodologies would be appropriate and if so, how the scoring methodology should differ and what criteria should be used to identify which scoring methodology an MA organization should use when determining its accuracy score for a specified MA plan.

In alignment with the statute, as CMS developed this proposed accuracy scoring methodology, CMS considered the relative importance of certain provider directory information on enrollee ability to access care and the administrative burden of verification on MA organizations and providers. As described at new proposed § 422.123(d)(4), CMS proposes to have a weighted provider directory accuracy scoring methodology, in which provider directory information elements are weighed according to their relative importance for beneficiary access to care. By choosing to weigh specific pieces of information, CMS emphasizes the accuracy of certain elements of provider directory information over others.

In summary, CMS is proposing to codify the provider directory accuracy score requirements at new proposed § 422.123(d)(3) and the provider directory accuracy scoring methodology requirements at new proposed § 422.123(d)(4). CMS solicits comments on these proposed changes.

6. Provider Directory Accuracy Reporting to CMS (§ 422.123(d)(5))

Section 1857(e)(6)(A)(ii) of the Act requires that beginning with plan years beginning on or after January 1, 2028, each MA organization must submit to the Secretary a report containing the results of the analysis conducted under clause (i), including an accuracy score for such provider directory information (as determined using a plan verification method specified by the Secretary under subparagraph (B)(i)).

CMS proposes to codify this requirement at new proposed § 422.123(d)(5)(i), requiring that the MA organization must submit to CMS an annual provider directory accuracy report containing the results of the accuracy analysis for its specified MA plans. CMS proposes that the report must contain the provider directory accuracy score for each specified MA plan. In addition to this basic statutory requirement, CMS is considering requiring additional elements for the annual provider directory accuracy report so that CMS can monitor MA organizations' implementation of the new provider directory accuracy requirements and can issue updated technical guidance taking into account the experience and burden of MA organizations. Furthermore, CMS is also aware of section 6220(b)(3) of the CAA, which states that the Comptroller General of the United States (or the Government Accountability Office, GAO) shall conduct a study and corresponding report including an analysis of the use of cost sharing protections; the trend in provider directory information accuracy scores submitted to CMS, both overall and among providers specializing in mental health or substance use disorder treatment; provider response rates by plan verification methods; administrative costs to providers and MA organizations; and other items determined appropriate by the Comptroller General (or GAO). Therefore, as CMS considers what reporting data to collect from MA organizations, CMS is bearing in mind what information the GAO may be interested in for purposes of the GAO study and corresponding report. Specifically, in addition to the provider directory accuracy score, CMS is considering requiring that the annual provider directory accuracy report also contain elements, including but not limited to provider specialty type response rates by verification method or other sampling data by provider specialty type (including possibly requiring reporting based on the NUCC

provider taxonomy code set), estimated administrative costs to the MA organization, estimated administrative costs to the MA organization's contracted providers, and data on the use of cost sharing protections. CMS requests comments on whether these additional reporting elements should be required. CMS will take into account commenters' feedback and may finalize the collection of these additional data elements in the final rule should such an outcome be supported.

In addition, regarding timing for MA organizations' annual submission of the provider directory accuracy report, at new proposed § 422.123(d)(5)(ii), CMS proposes that the report must be submitted not later than the first Monday in April of the year following the contract year being measured, in a form and manner specified by CMS. In proposing this date, CMS intends to give MA organizations at least three months to compile the required information and complete their provider directory accuracy report for the previous contract year. CMS solicits comments specifically on this proposed annual reporting deadline and whether it provides MA organizations with sufficient time. CMS also solicits comments on all aspects of these proposed changes regarding provider directory reporting at new proposed § 422.123(d)(5).

CMS is also considering whether to require that the annual provider directory accuracy analysis and resulting provider directory accuracy score be independently reviewed and certified by a qualified third party prior to submission to CMS. CMS believes that an independent review could promote consistency in the application of the sampling methodology, strengthen confidence in the reported accuracy scores, and provide an additional safeguard against variability in implementation across MA organizations. Similar to other CMS reporting requirements that require independent certification or attestation, the third party would be responsible for evaluating whether the MA organization's analysis was conducted in accordance with CMS requirements and that the reported results reasonably reflect the underlying provider directory information.

CMS seeks comments on whether an independent third-party certification requirement should be adopted, the qualifications such entities should possess, whether certification should be performed under generally accepted attestation or audit standards, and whether CMS should establish independence requirements comparable

to those used for other CMS certification and reporting requirements.

7. Exception for Specified MA Plans With Low Enrollment

Section 1857(e)(6)(C) of the Act specifies that the Secretary may waive the requirements of paragraph (e)(6) "Provider Directory Accuracy Analysis and Reports," in the case of a specified MA plan with low enrollment (as defined by the Secretary). CMS is considering whether to implement this statutory authority to exempt low-enrollment specified MA plans from the annual provider directory accuracy analysis and reporting requirements. Since the statute allows the Secretary to define what low enrollment means, CMS is contemplating various approaches for this definition if the low-enrollment exception were to be implemented. One approach might be to use a threshold for low enrollment that is already used in other areas of the MA program. For example, CMS could potentially apply similar criteria as the existing minimum enrollment threshold for MA plans, such as 500 enrollees for non-special needs plans (non-SNPs) and 100 enrollees for SNPs. Alternatively, CMS could apply similar criteria as is currently used for the Star Ratings threshold, which is 30 enrollees.

Considering these approaches, if CMS implements the low-enrollment exception so that specified MA plans with low enrollment do not have to complete the annual provider directory accuracy analysis and report, then some of the administrative burden on smaller plans may be eased, though all MA organizations offering specified MA plans, including low-enrollment plans, would still be subject to the verification and updating requirements in proposed § 422.123(b) and (c). There would also be a consistency in approach in terms of other areas of the MA program in which low enrollment thresholds are used. However, CMS believes that provider directory accuracy is important for all specified MA plans, regardless of the number of enrollees. It is important to balance the burden on specified MA plans and the need for enrollees to have accurate provider directories to ensure they can access care. CMS is inclined towards making the annual provider directory analysis and reporting requirements applicable to all specified MA plans, regardless of enrollment size, in which case CMS would not implement an exception to these new requirements for specified MA plans with low enrollment. CMS strongly supports the idea that accurate provider directories are important regardless of the plan size. In addition, the fact that

some traditionally smaller sized MA organizations tend to offer SNPs, which may include more vulnerable enrollees, leads CMS to believe that a waiver for enrollment size may not be in the best interest of the beneficiary. Taking into account all of these factors, CMS solicits comments on whether and, if so, how to implement the statutory authority to exempt low-enrollment specified MA plans from the annual provider directory accuracy analysis and reporting requirements.

8. Contract Requirement for MA Organizations (§ 422.504(a)(22))

Section 1857(e)(6)(A) of the Act requires that, beginning with plan years beginning on or after January 1, 2028, each CMS contract with an MA organization shall require the MA organization, for each specified MA plan it offers, to annually conduct a provider directory accuracy analysis using a random sample of providers in accordance with subparagraph (A)(i) and submit to the Secretary a report containing the results of such analysis, including a provider directory accuracy score. To codify this statutory requirement, CMS proposes to add new paragraph (a)(22) to the regulations for contract provisions at § 422.504, stating that in the contract between the MA organization and CMS, the MA organization agrees to comply with the provider directory accuracy requirements under § 422.123(d)—for contract year 2028 and subsequent contract years—for each specified MA plan. CMS solicits comments on this proposed change.

9. Provider Directory Public Transparency (§ 422.123(e))

Section 1857(e)(6)(D) of the Act requires that, beginning with plan years beginning on or after January 1, 2029, the Secretary shall post accuracy scores (as reported under subparagraph (A)(ii)), in a machine-readable file, on an internet website maintained by CMS. To codify this public transparency requirement, CMS proposes to add new § 422.123(e), which would state that beginning with contract years beginning on or after January 1, 2029, CMS will post provider directory accuracy scores as reported under paragraph (d)(5) of this section in a machine-readable file on the CMS website. If finalized as proposed, this would mean that in contract year 2029, CMS would post the contract year 2028 provider directory accuracy scores that MA organizations would be required to report to CMS by April 2029 in accordance with proposed § 422.123(d)(5). In addition to this proposed public online posting in a

machine-readable file, CMS is considering posting the scores through various Application Programming Interfaces (APIs) that CMS offers. CMS is currently also considering posting the provider directory accuracy scores of MA organizations on the MPF website. CMS solicits comments on this proposed change.

10. Enrollee Cost Sharing Protections When Provider Directories Are Inaccurate (§§ 422.124 and 422.202(f))

Section 1852(d) of the Act establishes provider directory cost sharing protections for enrollees who rely on incorrect provider directory information. Specifically, if a provider is in the provider directory of a specified MA plan on the date an enrollee makes an appointment, but at the time of the appointment when the item or service is furnished by the provider, it is determined that the provider is no longer in-network, then the MA organization must limit enrollee cost sharing to the lesser of the in-network or otherwise applicable cost sharing amount. These protections take effect beginning in contract year 2028 and apply to all subsequent contract years.

To implement the new cost sharing protections contained within section 1852(d) of the Act, CMS proposes to add new regulations at § 422.124, which would outline the scope of the protections, and the process enrollees must follow to access them. The protections would apply under proposed § 422.124(a) and (b) when an enrollee receives services from an out-of-network provider who was listed as in-network in the specified MA plan's directory on the date the appointment was made, and those services would otherwise be covered. In such cases, the MA organization would limit the enrollee's cost sharing to whichever amount is less, the in-network or otherwise applicable cost sharing amount. To initiate the process, the enrollee or their authorized representative would submit a request for the cost sharing protections to the MA organization, which would treat the request as an organization determination or reconsideration request per § 422.124(c). The MA organization would then determine eligibility by: (1) confirming the date the appointment was made per § 422.124(d); and (2) verifying whether the provider appeared in the specified MA plan's online directory on that date per § 422.124(e). If the MA organization cannot obtain the documentation necessary to make that determination from provider documentation,

attestation, or a provider directory archive, the protections would be applied in the enrollee's favor per § 422.124(f). Once the MA organization confirmed that the protections apply, the lower cost sharing would be reflected in the enrollee's bill and maximum out-of-pocket (MOOP) calculation consistent with § 422.124(g).

Regarding the scope of the protections, CMS proposes to add § 422.124(a) and (b) providing that the cost sharing protections would apply if an enrollee in a specified MA plan is furnished an item or service from a provider that is not participating in the MA plan's network, but that provider is listed in the MA plan's provider directory as defined in § 422.2 on the date the appointment is made. The protections apply if the item or service would otherwise be covered under the MA plan if furnished by an in-network provider. In such cases, the MA organization offering the MA plan must ensure that the enrollee pays no more than the lesser of either: (1) the amount of cost sharing that would apply if the provider had been participating in the network of the plan; or (2) the amount of cost sharing that would otherwise apply.

CMS proposes adding § 422.124(c) to require the MA organization to apply the provider directory cost sharing protections without requiring an enrollee request when the MA organization knows or reasonably should know that the protections apply. In other words, if an enrollee or authorized representative references the use of incorrect provider directory information when requesting an organization determination or reconsideration for an out-of-network cost sharing bill but does not appear to be aware of the provider directory cost sharing protections, the MA organization must inform the enrollee of the available protections and evaluate whether the protections apply to the claim or claims. CMS also proposes to permit an enrollee or the enrollee's authorized representative to request application of the protections verbally or in writing to their MA organization. CMS proposes at § 422.124(c)(1) that such requests would be processed as organization determinations or reconsideration requests, as applicable, consistent with subpart M of this part. Consistent with current practice, when an enrollee or provider believes an item or service may not be covered, or could be covered only under specific conditions, a pre-service organization determination should be requested from the MA organization. If the item or service is denied, the standardized

denial notice must include information about the enrollee's appeal rights.

To confirm the date on which the appointment was made, CMS proposes to require at § 422.124(d) that MA organizations include a term in each provider contract for a specified MA plan obligating the provider to supply documentation of the earliest date on which the enrollee's appointment was scheduled, regardless of any subsequent rescheduling. For example, if an enrollee makes an appointment on April 12, 2028, and reschedules the appointment on May 15, 2028, the MA organization would look at the provider directory on April 12, 2028, to see if the provider was listed as in-network. At § 422.124(d), CMS proposes that acceptable documentation would include a paper or electronic record from the provider's scheduling system or confirmation sent to the enrollee or their authorized representative from the provider. If a record of the date the appointment was made is not reasonably obtainable, a signed attestation from the provider, accompanied by any available corroborating information such as a calendar entry, a referral record, electronic communications, or a phone log, if available would be sufficient to show the approximate date the appointment was made. CMS proposes that this contract term survives the expiration or termination of the contract between the MA organization and the provider for not less than 10 years, beginning on the date the contract expiration or termination becomes effective, thereby ensuring that providers who were previously participating in the specified MA plan's network remain obligated to supply documentation regarding the date on which the enrollee's appointment was made, even after departing from the network.

In order to verify the accuracy of the provider directory, at § 422.124(e) CMS proposes to add a requirement that the MA organization would determine whether the provider was listed as an in-network provider in the specified MA plan's online provider directory on the date the appointment was made by referencing archived electronic provider directory data maintained online by the MA organization. Archived provider directory data must be sufficient to identify whether any provider was listed in the specified MA plan's online directory at any point on a given date, retained for not less than ten years consistent with § 422.504(d), and made available to CMS upon request within 5 business days. If the archived provider data provided indicates that the

provider in question was listed in the specified MA plan's online provider directory at any point during a given day, whether in the morning or later in the afternoon, the provider would be considered to have been listed in the online directory for that entire day for the purpose of determining whether the cost sharing protections apply. In addition, a notice that the provider information may be outdated, per the requirement at new proposed § 422.123(b)(3) in this proposed rule, would not affect an enrollee's eligibility for the cost sharing protections.

CMS solicits comments on whether the provider directory data used to determine whether the cost sharing protection applies should be limited to the online provider directory as proposed here, or whether the cost sharing policy should similarly apply to the contents of a physical hardcopy of the provider directory upon which an enrollee relied given that MA organizations have an obligation to provide enrollees with a physical hardcopy of a current provider directory upon request in accordance with § 422.2267(d). For example, under the proposed requirement at § 422.123(c)(2), an MA organization must send a quarterly addendum with provider directory updates to all enrollees who have requested a physical hardcopy provider directory. CMS is seeking comments on whether, under this proposed framework, an enrollee who uses the most current physical hardcopy directory available (that is, a physical hardcopy version with up-to-date addenda) to schedule an appointment—even if that physical hardcopy differs from the online directory on the date of the appointment—should qualify for the cost sharing protections described in proposed § 422.124. CMS also solicits comments on the duration of the proposed data retention requirement and whether MA organizations should be required to publicly post daily versions of their provider directories instead of being made available to CMS upon request within 5 business days as proposed. CMS believes that inclusion of such a requirement may be necessary to ensure accuracy and ease the review of archived provider directories. Finally, CMS seeks public comment on whether formatting requirements for archived provider directory information should be established, such as through a log of provider updates or removals or another auditable archive sufficient to identify the directory status of a provider on a given date.

CMS proposes at § 422.124(f) that if the MA organization is unable to obtain documentation demonstrating the date

on which the appointment was scheduled or is unable to verify archived provider directory data within the applicable standard or expedited organization determination timeframes provided under 42 CFR 422 subpart M, the provider directory cost sharing protections must be applied in favor of the enrollee. This default application may be reversed only if the MA organization is able to clearly demonstrate that the cost sharing protections do not apply.

To apply the cost sharing protections, at § 422.124(g)(1) CMS proposes that if the MA organization collects cost sharing from an enrollee in excess of the amount permitted under the provider directory cost sharing protections, and the protections apply, the MA organization must refund the excess amount to the enrollee consistent with § 422.270(b). Additionally, when the protections apply and a refund is issued, at § 422.124(g)(2) CMS proposes that MA organizations treat that cost sharing as in-network cost sharing for purposes of any applicable MOOP limit, consistent with § 422.100(f)(4).

The purpose of the cost sharing protections created by the REAL Health Providers Act is to protect MA enrollees who rely on the provider directory of a specified MA plan to schedule an appointment with an in-network provider and later discover that the provider is out-of-network. The following example illustrates a scenario when the cost sharing protection would apply. An MA enrollee needs to see a cardiologist, checks their MA plan's online provider directory, and finds Dr. Smith listed as an in-network provider. On January 5, 2028, they schedule an appointment with the provider's office for March 6, 2028. The enrollee receives items and services from Dr. Smith on March 6, 2028, and subsequently receives an EOB reflecting cost sharing at the out-of-network rate, higher than the in-network rate the enrollee expected. The enrollee contacts their MA organization to see why the bill is so high and explains that the doctor was listed on their plan's provider directory at the time the appointment was made. The MA organization educates the enrollee about the provider directory cost sharing protections and offers to determine whether the enrollee qualifies. The enrollee agrees and the MA organization works with the enrollee's provider's office to confirm the appointment was made on January 5, 2028, and verifies via its archived provider directory data that Dr. Smith was listed as in-network on the same date. The MA organization then applies the protections, capping the enrollee's

cost sharing at the in-network rate, refunding any excess cost sharing the enrollee may have already paid, and counts the cost sharing toward the enrollee's in-network MOOP limit.

Notably, if Dr. Smith's office has no scheduling records available or an archive of the plan directory was unavailable, the MA organization would still be required to apply the protections in the enrollee's favor unless the MA organization was able to clearly demonstrate that the cost sharing protections do not apply, such as proof that the provider was never in the specified MA plan network.

These proposed requirements are designed to strengthen enrollee protections and reduce the risk of unexpected higher out-of-network costs resulting from inaccurate provider directory information. CMS believes these proposals align with the statutory goal of ensuring all enrollees have timely access to the new cost sharing protections and incentivizing MA organizations to maintain accurate and up-to-date directories on an ongoing basis. CMS proposes that the burden of proof for determining whether these protections apply rests with the MA organization, not the enrollee, and that MA organizations must make reasonable, good-faith efforts to gather all relevant documentation prior to rendering an eligibility determination from the provider consistent with the contract term requirements at § 422.124(d). The impact of the proposed policy changes is discussed in the Collection of Information Requirements and Regulatory Impact Analysis under sections III.A. through D. and IV.A. through K. of this proposed rule, respectively. CMS seeks comments on ways to improve enrollee access to the cost sharing protections, the operational feasibility of these requirements, including the processes MA organizations would use to verify whether an enrollee relied on directory information at the time an appointment was made, and whether additional documentation or verification standards are necessary to ensure the integrity and effective administration of these protections.

11. Provider Directory Disclosure Requirements (§§ 422.111(b)(3)(i), (b)(12), and (k) and 422.120(b)(1))

The REAL Health Providers Act also affects CMS's current MA disclosure requirements. First, section 1852(c)(1)(C) of the Act requires MA organizations, for plan year 2028 and subsequent plan years, in the case of a specified MA plan, to disclose to enrollees the information described in

paragraph (c)(3)(B) (that is, provider directory information). CMS's current regulatory text corresponding to this section of the statute is located at § 422.111(b)(3)(i), where the disclosure requirement for the provider directory currently states "the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office."

To codify the new provider directory disclosure requirement in the statute, CMS proposes to amend § 422.111(b)(3)(i) to include both phrases "the number, mix, and distribution of providers from whom enrollees may reasonably be expected to obtain covered benefits" and "provider directory information as defined in § 422.2 and in accordance with § 422.2267(e)(11)." The reason for the proposed removal of "(addresses)" is to avoid duplication because the proposed definition of provider directory information at § 422.2 includes "Primary office or facility address(es) where covered items or services are furnished" as one of the proposed required pieces of information. Further, CMS's proposed cross-reference to the definition of provider directory information at § 422.2 aligns with the statute, and the additional proposed cross-reference to § 422.2267(e)(11) would ensure that provider directory requirements related to timing of required disclosure, verification, and updates are also captured. In addition, as discussed in section II.B.1. of this proposed rule, CMS is proposing to remove the phrase "each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office" from § 422.111(b)(3)(i). CMS believes that the codification of the statutory term "cultural and linguistic capabilities" from section 1852(c)(3)(B) of the Act for the proposed definition of "provider directory information" at § 422.2 suffices. For ease of reading of the regulatory text, CMS's proposal at § 422.111(b)(3)(i) includes a breakdown of the different disclosure elements in the form of paragraphs (b)(3)(i)(A) through (E), wherein "the number, mix, and distribution of providers from whom enrollees may reasonably be expected to obtain covered benefits" and "provider directory information as

defined in § 422.2 and in accordance with § 422.2267(e)(11)" would be located at proposed subparagraphs (b)(3)(i)(A) and (B), and the remaining subparagraphs would contain existing § 422.111(b)(3)(i) regulatory text that CMS is not proposing to modify.

The REAL Health Providers Act also establishes provider directory disclosure requirements related to the cost sharing protections and the accuracy score. First, section 1852(d)(7)(B)(i) and (ii) of the Act requires that for plan year 2028 and subsequent plan years, each MA organization that offers a specified MA plan shall: (1) notify enrollees of their cost sharing protections under this paragraph and make such notifications, to the extent practicable, by not later than the first day of an annual, coordinated election period under section 1851(e)(3) of the Act with respect to a year; and (2) include information regarding such cost sharing protections in the provider directory of each specified MA plan offered by the MA organization. Second, section 1851(d)(4)(F) of the Act requires that, beginning with plan years beginning on or after January 1, 2029, in the case of a specified MA plan, the accuracy score of the plan's provider directory (as reported under section 1857(e)(6)(A)(ii) of the Act) must be listed prominently on the MA plan's provider directory.

To codify these new provider directory disclosure requirements, CMS is proposing to add new paragraph (b)(12) to § 422.111, titled "Cost sharing protections and accuracy score in provider directory." In new proposed § 422.111(b)(12), each MA organization offering a specified MA plan would be required to disclose, in a form and manner specified by CMS, information within the provider directory regarding cost sharing protections and accuracy, including: (1) for contract year 2028 and subsequent contract years—by no later than the first day of the annual coordinated election period under § 422.62(a)(2)—a plain-language description of the enrollee cost sharing protections required under § 422.124; and (2) for contract year 2029 and subsequent contract years, the most recent provider directory accuracy score reported to the Secretary in accordance with § 422.123(d)(5), prominently displayed. Pursuant to CMS's current regulations at § 422.2267(e)(11), MA organizations are required to provide the provider directory to current enrollees no later than the start of the annual coordinated election period. Thus, by including the specified cost sharing protection and accuracy information to enrollees in the provider directory as proposed in

§ 422.111(b)(12), CMS is proposing that MA organizations would also be considered to satisfy the statutory requirement under section 1852(d)(7)(B)(i) of the Act that such notification must be made by MA organizations, “to the extent practicable, by not later than the first day of an annual, coordinated election period under section 1851(e)(3) of the Act with respect to a year.”

For the proposed disclosure requirement at new proposed § 422.111(b)(12)(ii) that the MA organization prominently display the most recent provider directory accuracy score, CMS believes the most appropriate place for the accuracy score would be at the end of the introduction to the provider directory, before the list of network providers. In addition, CMS believes that providing a simple explanation alongside the accuracy score would be sufficient, for example, “Information Accuracy: [insert letter grade score]. We have rated this directory based on how correct the information we provide is. We always aim to give you the most accurate details possible.” If § 422.111(b)(12) is finalized as proposed, then CMS intends to update the Medicare Advantage and Section 1876 Cost Plan Provider Directory Model and Instructions with similar template language for the new disclosure requirements for the provider directory.

In addition, consistent with section 1852(d)(7)(B)(iii) of the Act, CMS is proposing to amend the heading of § 422.111(k) to clarify that the paragraph addresses the Explanation of Benefits (EOB) and add § 422.111(k)(6) to require that a notification about the cost sharing protection be included in the first EOB issued in a plan year.⁹ CMS proposes that the first EOB issued in a plan year for each specified MA plan would include a plain-language description of the provider directory cost sharing protections available to enrollees under § 422.124; a toll-free telephone number and website URL through which an enrollee or their representative may request application of the protections, and information describing how an enrollee or their representative may request a correction if cost sharing was applied in a manner inconsistent with those protections. If § 422.111(k)(6) is finalized as proposed, then CMS intends to update the EOB model document with template language, such as “If you receive items or services from an out-of-network provider who was listed in your plan’s provider directory as in-network on the date your appointment

was made, and those services would otherwise be covered, your cost sharing is limited to the in-network cost sharing amount.” In addition, CMS would update the Medicare Advantage and Section 1876 Cost Plan Provider Directory Model and Instructions with similar template language regarding the enrollee cost sharing protections if § 422.111(b)(12)(i) is finalized as proposed. CMS has also considered adding notification about the cost sharing protection in the Summary of Benefits (SB) as well as the Evidence of Coverage (EOC), as that would ensure that beneficiaries receive both pre-enrollment (via the SB) and post-enrollment (via the EOC) notification. CMS solicits comments on including the notification in these two additional materials.

Lastly, after reviewing all existing provider directory sections in the regulation, CMS believes that a conforming change to the provider directory API requirements at § 422.120(b)(1) is necessary to ensure consistency in regulatory language. Currently, § 422.120(b)(1) requires that the API must provide a complete and accurate directory of the MA plan’s network of contracted providers, including “names, addresses, phone numbers, and specialties, updated no later than 30 calendar days after the MA organization receives provider directory information or updates to provider directory information.” CMS proposes to amend § 422.120(b)(1) to remove the references to names, addresses, phone numbers, specialties, and the 30-day updating requirement, and replace this information with cross-references to the proposed definition for provider directory information at § 422.2 and the proposed provider directory verification and updating requirements at new proposed § 422.123(b) and (c). This proposed modification simplifies the regulatory text, ensures consistency, and avoids the need to update regulatory language in multiple sections in the future. CMS believes that this change is also a productive step towards ensuring that the proposed definition of provider directory information at § 422.2 is applied consistently to all formats of the provider directory (including the API) that an MA organization produces.

In summary, CMS is proposing to codify the provider directory disclosure requirements at § 422.111(b)(3)(i), (b)(12), and (k), and to make a conforming change to the provider directory API requirements at § 422.120(b)(1). CMS solicits comments on these proposed changes.

12. Conclusion

As discussed in section II.B. of this proposed rule, CMS believes that the accuracy scoring and verification framework required under the REAL Health Providers Act will serve to strengthen the integrity of the underlying provider data that both MPF and the NPD will likely come to depend upon, helping to ensure a consistent and reliable foundation for the larger health tech ecosystem. In addition, CMS recognizes that the data flow contemplated under this framework—in which MA organizations submit data to CMS, the NPD conceivably ingests that data and may enrich that data from additional sources, and MA organizations then publish NPD-informed directories—could raise questions about the appropriate scope of MA organization accountability for accuracy scores. CMS wishes to clarify that MA organization accountability under the REAL Health Providers Act as proposed herein attaches to the data the MA organization submits, verifies, and attests to, and to the rigor of the MA organization’s own verification processes, rather than to data elements that may be added or modified by the NPD from sources outside the MA organization’s control. MA organizations will retain an independent obligation under the REAL Health Providers Act to verify their provider directory information on the prescribed cycle as defined under § 422.123(b), if finalized. In addition, as CMS’s various provider directory initiatives mature, CMS anticipates a process that will allow MA organizations to reconcile any discrepancies between NPD-returned data and their own verified records prior to publication if such discrepancies are identified. CMS will provide further guidance on the delineation of accountability between MA organization-originated and NPD-enriched data elements as the NPD infrastructure continues to be developed, implemented, and operationalized. This delineation of accountability approach could possibly include a safe-harbor component, as NPD infrastructure matures to be able to accept validated data programmatically from health care providers and organizations.

CMS seeks comments on whether this proposed approach effectively integrates the REAL Health Providers Act requirements with the existing § 422.111(m) framework and the developing NPD initiative in a way that is practical and achieves the statute’s goals. CMS is particularly interested in

⁹ § 422.2267(e)(2).

whether any conflicts or gaps exist among these three frameworks that this proposed implementation does not adequately address, and whether additional guidance is needed prior to the contract year 2028 effective date of the REAL Health Providers Act mandates. More broadly, CMS welcomes input on any aspects of provider directory accuracy, verification burden, data standardization, or beneficiary transparency that interested parties believe CMS has not fully considered, including potential specific mechanisms for an effective technology-based safe harbor that allows for the NPD to mediate accountability.

C. Modernizing and Ensuring PBM Accountability (Section 6224 of the Consolidated Appropriations Act, 2026)

1. Background

Section 6224 of CAA (Pub. L. 119–75, enacted February 3, 2026) added sections 1860D–12(h) and 1857(f)(3) of the Act, which establish new and enhanced requirements under the Medicare Part D program that address, among other issues, compensation and data transparency for pharmacy benefit managers (PBMs). CMS is proposing to implement these requirements through this rulemaking.

PBMs provide services such as drug price negotiation, prescription claims adjudication, formulary development, and pharmacy network contracting for insurance plans, including Part D plan sponsors that manage the Part D prescription drug benefit. Federal agencies, academics, and others have raised concerns that PBM business practices and corporate structure have contributed to the high cost of prescription drugs in the United States.¹

In 2022, the Federal Trade Commission (FTC) issued special orders pursuant to section 6(b) of the Federal Trade Commission Act to the six largest PBMs to gather information about their business practices. After studying the information received, the FTC released two reports: a 2024 report titled “Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies” and a 2025 report titled “Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers.”¹⁰ These reports discussed several concerning aspects of the PBM industry, including

a market featuring a high degree of concentration and vertical integration (with the three largest PBMs, which are integrated with both pharmacies and health plans, processing about 80 percent of prescription drug claims in the United States), higher payment rates for pharmacies that are affiliated with PBMs (especially specialty pharmacies) compared to unaffiliated pharmacies, opaque contract terms that disadvantage smaller and independent pharmacies, formulary placement decisions that favor higher-cost branded drugs over generics in exchange for higher rebates, and significant spread pricing in which PBMs retain a portion of the amount that a health plan pays the PBM for a drug rather than passing on the full amount to the pharmacy for specialty generics.

The FTC reports also expressed concern with PBM-affiliated rebate aggregators, also referred to as PBM group purchasing organizations (PBM GPOs), which do not function as traditional GPOs but rather as spin-off entities to which PBMs have shifted the function of rebate negotiation with pharmaceutical manufacturers. There are three PBM GPOs in this category, affiliated with the three largest PBMs in the United States. The first FTC report¹¹ referenced previously discussed the recent formation of these entities—which the FTC noted likely occurred in an attempt to take advantage of the antikickback safe harbor for GPOs. The FTC issued supplemental orders to collect information from those three PBM GPOs in 2023 but noted in its second report that the PBM GPOs had provided only a partial response to these orders.¹² While PBM GPOs themselves are relatively new, they are representative of a consistent pattern of utilization of complex affiliate structures and vertical and horizontal integration in the PBM industry and demonstrate PBMs’ ability to adapt in the face of changing legislative and regulatory dynamics.

Academics have similarly raised concerns with PBMs’ impact on the price of drugs. Revenue retained by PBMs at several points in the pharmaceutical supply chain—including pharmacy spread pricing, retention of a portion of the rebate negotiated with the pharmaceutical manufacturer, and increasing ownership of 340B contract pharmacies—is often not transparent to health plans and may

contribute to high drug prices.¹³ Because PBM compensation is often linked to the price of the drug, there are perverse incentives for PBMs to favor higher cost drugs;¹⁴ one recent article estimated that if compensation for wholesalers, pharmacies, and PBMs were delinked from list prices, net drug spending could be reduced by approximately 15 percent.¹⁵ As similarly noted by the FTC, the PBM market is also highly concentrated and vertically integrated; almost all major PBMs operate their own mail order or specialty pharmacies (and some retail pharmacies), and the largest health insurers in the country either own PBMs or share a common ownership structure with PBMs.¹⁶

In addition to the reports that the FTC has issued following its issuance of 6(b) orders, the FTC has also filed lawsuits against the three largest PBMs and their affiliated PBM GPOs in September 2024, alleging that their rebating practices for insulin products were anticompetitive, unfair, and artificially inflated list prices. Specifically, the FTC claimed that PBMs gave insulin products with higher list prices favorable formulary placement due to the potential to extract and retain higher rebates and price-linked fees associated with such products, which caused pharmaceutical manufacturers to artificially inflate list prices and prevented patients from accessing insulin products with lower list prices and lower cost-sharing. The FTC reached settlements with two of the PBMs—Express Scripts, Inc. (ESI), announced in February 2026,¹⁷ and Caremark, announced in July 2026.¹⁸ The proposed ESI consent order include requirements to prohibit formulary placement on the basis of wholesale acquisition cost (WAC) (also known as list price), to pass through rebates at the point of sale so that they will be incorporated into patient cost-sharing, to provide a standard offering to plan sponsors allowing them to transition away from rebate guarantees and spread pricing, to delink fees paid from

¹³ <https://pmc.ncbi.nlm.nih.gov/articles/PMC11482839/>.

¹⁴ <https://www.commonwealthfund.org/publications/explainer/2025/mar/what-pharmacy-benefit-managers-do-how-they-contribute-drug-spending>.

¹⁵ <https://pmc.ncbi.nlm.nih.gov/articles/PMC12287691/pdf/qxaf126.pdf>.

¹⁶ <https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/>.

¹⁷ <https://www.ftc.gov/news-events/news/press-releases/2026/02/ftc-secures-landmark-settlement-express-scripts-lower-drug-costs-american-patients>.

¹⁸ <https://www.ftc.gov/news-events/news/press-releases/2026/07/ftc-secures-major-settlement-caremark-resolving-antitrust-case-against-second-drug-middleman>.

¹ <https://www.ftc.gov/reports/pharmacy-benefit-managers-report>.

² <https://www.ftc.gov/reports/pharmacy-benefit-managers-report>.

³ <https://www.ftc.gov/reports/pharmacy-benefit-managers-report>.

¹² <https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers>

pharmaceutical manufacturers to PBM GPOs from drug prices, and to maintain PBM GPO activities in the United States (two of the three major PBM GPOs had been established off shore), among other requirements.¹⁹

CMS has already made some efforts to address PBM practices in Medicare. In the May 9, 2022, **Federal Register** (87 FR 27704), we addressed opaque performance-based penalties and price concessions from pharmacies that PBMs sometimes applied after the point of sale, preventing pharmacies from having access to predictable, transparent payment structures. CMS analysis showed that pharmacy price concessions grew more than 107,400 percent between 2010 and 2020. These practices rendered prescription drug prices less transparent and less representative of the actual amount the plan sponsor paid to the pharmacy for the drug dispensed. The new requirements, finalized in the final rule, “*Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs*,” restructured the financial relationship between plan sponsors, PBMs, and pharmacies by mandating transparency for all pharmacy price concessions at the point of sale.

The new requirements changed the definition of the negotiated price for a covered Part D drug at 42 CFR 423.100 to include all pharmacy price concessions at the point of sale, and not just those that could be reasonably determined at the point of sale. Beginning in 2024, a patient’s cost share is based on the lowest possible reimbursement that a pharmacy could receive for that drug. CMS has noted a significant decrease in plan-reported pharmacy price concessions. Pharmacy direct and indirect remuneration (DIR) changed from a positive amount in CY 2023 (meaning Part D plan sponsors and PBMs recouped more from pharmacies in price concessions than they paid to pharmacies in bonus payments) to a negative amount in CY 2024 (meaning Part D plan sponsors and PBMs recouped less from pharmacies in price concessions than they paid to pharmacies in bonus payments).²⁰ Pharmacy payment for covered Part D drugs is now more transparent and predictable for pharmacies.

Section 6224 of the CAA builds on prior efforts to address PBM practices. The law introduces enhanced requirements for remuneration that PBMs may receive for services in connection with the utilization of covered Part D drugs. Generally, section 6224 of the CAA requires that such remuneration be restricted to bona fide service fees that may not be tied to the price of a drug or the rebates, discounts, or other price concessions negotiated. The law also introduces requirements for increased transparency, such as a new requirement for PBMs to report certain information such as drug prices and utilization, DIR, formulary placement of branded and generic drugs, information about payment rates at affiliated and unaffiliated pharmacies, and information on affiliates and brokers, to both Part D plan sponsors and the Secretary of Health and Human Services (HHS) annually. These requirements are to be effectuated through written agreements between Part D plan sponsors—inclusive of both sponsors offering standalone Part D prescription drug plans (PDPs) and sponsors offering Medicare Advantage prescription drug (MA–PD) plans that combine Medicare Advantage and Part D prescription drug benefits—and PBMs beginning with contract year 2028.

An overview of the new requirements included in section 6224 of the CAA related to Part D plan sponsor contract requirements and federal oversight and enforcement mechanisms is provided later in this section, as well as a summary of the proposed policies that are required to implement this law. The remainder of this discussion is organized to address the major provisions of the law in more detail.

- Section II.C.2. of this proposed rule defines key terms.
- Section II.C.3. of this proposed rule discusses the definition of a pharmacy benefit manager.
- Section II.C.4. of this proposed rule discusses the definition of an affiliate.
- Sections II.C.5 through C.10. of this proposed rule discuss remuneration and transparency requirements of the written agreement between Part D plan sponsors and PBMs acting on behalf of such sponsors.
- Section II.C.11. of this proposed rule addresses additional compliance and enforcement mechanisms available to Part D plan sponsors and CMS.
- Section II.C.12. of this proposed rule addresses confidentiality of information shared under the new requirements of the CAA.
- Section II.C.13. of this proposed rule addresses severability.

a. Overview of Part D Plan Sponsor Contract Requirements for Written Agreements With PBMs

Section 6224 of the CAA amended section 1860D–12 of the Act by adding a new subsection (h)(1), which specifies that beginning with contract year 2028, any Part D plan sponsor with a contract under section 1860D–12 of the Act to offer a prescription drug plan must have a written agreement, containing certain requirements, with any PBM acting on its behalf. The requirements that must be in the written agreement with the PBM address remuneration derived by PBMs and their affiliates in connection with the utilization of Part D drugs, transparency regarding guarantees and cost performance evaluations, reporting of information by PBMs to Part D plan sponsors and the Secretary, and enforcement mechanisms provided to the Part D plan sponsor. We briefly describe each of the topics that the written agreement between the Part D plan sponsor and the PBM must address; each topic is addressed in greater detail in subsequent sections of this rule.

(1) Remuneration

Section 1860D–12(h)(1)(A)(i) of the Act, as added by the CAA, generally requires that PBMs and any affiliates of such PBMs not derive any remuneration with respect to any services provided on behalf of any entity or individual, in connection with the utilization of covered Part D drugs, other than bona fide service fees. Included in the definition of bona fide service fees is that such fees must be flat dollar amounts, reflective of fair market value (as specified by the Secretary through notice and comment rulemaking), for an itemized service, and that they may not be contingent on the amount of rebates, discounts, fees, or other direct or indirect remuneration; drug price; coverage or formulary placement; and any other amounts or methodologies prohibited by the Secretary.

There are certain exceptions to the requirement that PBMs and their affiliates only receive remuneration in the form of bona fide service fees. First, section 1860D–12(h)(1)(A)(ii) of the Act allows PBMs or their affiliates to receive incentive payments paid by a Part D plan sponsor if they meet certain requirements. Second, section 1860D–12(h)(1)(A)(iii) of the Act provides that rebates, discounts, or other price concessions received by a PBM or an affiliate of a PBM from manufacturers are not considered a violation of the bona fide service fee requirement if they are fully passed through to a Part D plan

¹⁹ <https://www.federalregister.gov/documents/2026/02/12/2026-02844/express-scripts-inc-et-al-analysis-of-agreement-containing-consent-order-to-aid-public-comment>; https://www.ftc.gov/system/files/ftc_gov/pdf/CaremarkandZinc-DivisionandOrder.pdf.

²⁰ Internal CMS data.

sponsor and are compliant with all regulatory and sub-regulatory requirements related to DIR for manufacturer rebates, discounts, and other price concessions. Third, these remuneration requirements do not prohibit flat dispensing fees or reimbursement or payment for ingredient costs to PBMs or affiliates of PBMs that acquire or dispense prescription drugs, nor do they modify regulatory requirements or sub-regulatory program instruction or guidance related to pharmacy payment, reimbursement, or dispensing fees, in accordance with the rule of construction at section 1860D–12(h)(4) of the Act.

Section 1860D–12(h)(1)(A)(iv) of the Act requires that components of subsets of remuneration agreements between PBMs or their affiliates and other entities involved in the dispensing or utilization of covered Part D drugs be subject to review by the Secretary, in consultation with the Office of the Inspector General of the Department of Health and Human Services, as determined appropriate by the Secretary, for consistency with fair market value. It also requires that the PBM disgorge any remuneration received by the PBM or its affiliate that is in violation of the requirements added by the CAA to the Part D plan sponsor.

(2) Transparency

The CAA also introduces new requirements regarding transparency that must be reflected in the written agreements between Part D plan sponsors and PBMs. Part D plan sponsors must include in their written agreements with PBMs a requirement that PBMs “define, interpret, and apply” terms in a fully transparent and consistent manner for purposes of evaluating PBM performance against pricing guarantees or similar cost performance measurements. Pricing guarantees are agreements under which PBMs guarantee Part D plan sponsors a certain price for drugs—often represented as a percent off list price for specific categories of drugs, such as brand, generic, or specialty drugs—and either retain or reimburse the Part D plan sponsor for the difference between that price and the actual price negotiated with a pharmacy. As discussed later in this rule, PBMs’ interpretation of certain terms such as ‘generic’ or ‘specialty’ can significantly impact their ability to retain revenue through price guarantees.

Section 1860D–12(h)(1)(C) of the Act, as added by the CAA, requires that PBMs annually submit a report to the Part D plan sponsor and the Secretary of

HHS beginning no later than July 1 of 2028. This report is to include information on dispensed drugs covered by the plan, information about affiliate pharmacies, information on cost-sharing and formulary placement for reference listed drugs and reference products compared to their generic or biosimilar biological products, plan spending, PBM remuneration, benefit design parameters, information on brokers and consultants, and a list of affiliates.

Finally, PBMs must also provide a written explanation of certain information to Part D plan sponsors within 30 days of finalization of a contract or agreement between the PBM or an affiliate of the PBM and a manufacturer that makes rebates, discounts, payments, or other financial incentives related to one or more covered Part D drugs or other prescription drugs, as applicable, directly or indirectly contingent upon coverage, formulary placement, or utilization management conditions on any other covered Part D drugs or other prescription drugs.

(3) Enforcement by the Part D Plan Sponsor

In addition to the previous requirements, the CAA also requires that the written agreement between the Part D plan sponsor and PBM include certain mechanisms that the Part D plan sponsor may use to enforce the new requirements. Section 1860D–12(h)(1)(D) of the Act, as added by the CAA, requires that not less than once a year, at the request of the Part D plan sponsor, the PBM allow for an audit of the PBM to ensure compliance with all terms and conditions of the written agreement. Additionally, sections 1860D–12(h)(2)(A)(ii) and (iii) of the Act provide that the written agreement between the Part D plan sponsor and the PBM must require that the PBM or any affiliate of such PBM reimburse the Part D plan sponsor for any civil money penalty imposed on the Part D plan sponsor as a result of the failure of the PBM or affiliate to meet the requirements of section 1860D–12(h)(1) of the Act that are applicable to the PBM or affiliate, and must require in a written agreement with the PBM that the PBM or its affiliate be subject to punitive remedies for breach of contract for failure to comply with the requirements under section 1860D–12(h)(1) of the Act.

b. Overview of Federal Enforcement and Compliance Mechanisms

Sections 1860D–12(h)(2) and (3) of the Act, as added by the CAA, introduce certain enforcement and compliance

mechanisms related to section 1860D–12(h) of the Act. Section 1860D–12(h)(2)(A)(i) of the Act requires that each Part D plan sponsor shall disgorge to the Secretary any amounts disgorged to the Part D plan sponsor by a PBM due to violations of the remuneration requirements under section 1860D–12(h)(1)(A) of the Act. Additionally, section 1860D–12(h)(2)(B) of the Act specifies that the Secretary shall make available and maintain a mechanism for manufacturers, Part D plan sponsors, pharmacies, and other entities that have contractual relationships with PBMs or their affiliates to report, on a confidential basis, alleged violations of section 1860D–12(h)(1)(A) or (C) of the Act to the Secretary. Section 1860D–12(h)(2)(C) of the Act requires that a Part D plan sponsor shall not retaliate against an individual or entity for such reporting of an alleged violation, nor coerce, intimidate, threaten, or interfere with the ability of an individual or entity to report any such alleged violations. In addition, section 1860D–12(h)(3) of the Act requires that each Part D plan sponsor furnish to the Secretary an annual certification of compliance with section 1860D–12(h) of the Act, as well as information the Secretary determines necessary to carry out section 1860D–12(h) of the Act; the Secretary may implement this requirement by program instruction.

c. Summary of Proposed Policies Related to Section 6224 of the CAA

CMS is proposing to implement section 1860D–12(h) of the Act as follows:

- Proposed § 423.2800 establishes the basis and scope of the new subpart BB, titled “Modernizing and Ensuring Pharmacy Benefit Manager Accountability.”
- Proposed § 423.2802 defines several key terms that are set forth in the statute and warrant additional definition to effectively implement the law and clearly delineate its applicability.
- Proposed §§ 423.2804 and 423.2806 provide further detail on the definitions of PBM and affiliate.
- Proposed § 423.2808 describes the contractual requirements for Part D plan sponsors, further described in subsequent sections.
- Proposed § 423.2810 addresses requirements related to remuneration, including specifying fair market value for bona fide service fees and incentive payments.
- Proposed § 423.2812 establishes requirements for PBMs to provide transparency regarding guarantees and cost performance evaluations.

- Proposed § 423.2814 establishes requirements for PBMs to report information to Part D plan sponsors and the Secretary annually, beginning no later than July 1, 2028, and further defines certain terms related to such reporting.

- Proposed §§ 423.2810, 423.2816, 423.2818, and 423.2820 address requirements for compliance and enforcement mechanisms to be used by both Part D plan sponsors (such as audit rights) and CMS (such as annual requirements for Part D plan sponsor certifications of compliance and disgorgement of fees in violation of the remuneration requirements established at proposed § 423.2810).

- Proposed § 423.2822 addresses confidentiality and use of information disclosed by PBMs or their affiliates to Part D plan sponsors or CMS.

We published a request for information (RFI) on Pharmacy Benefit Manager Compensation and Data Collection on June 18, 2026 (91 FR 36776) to solicit technical input on the services and business practices of PBMs and their affiliates to inform this rulemaking.²¹ The comments that we received in response to that RFI informed the proposals in this rule, and we thank commenters for their input.

2. Definitions

In this proposed rule, CMS proposes to codify the definitions of terms consistent with the meanings given in section 1860D–12(h) of the Act. At proposed § 423.2802, CMS proposes definitions for the following terms in section 1847A of the Act that are discussed in greater detail in subsequent sections of this proposed rule:

- *Affiliate*, discussed in section II.C.4. of this proposed rule.
- *Bona fide service fee*, discussed in section II.C.6. of this proposed rule.
- *Fair market value*, discussed in section II.C.6. of proposed rule.
- *Fully passed through*, discussed in section II.C.6. of this proposed rule.
- *Incentive payment*, discussed in section II.C.6. of this proposed rule.
- *Intermediary*, discussed in section II.C.3. of this proposed rule.
- *Pharmacy benefit manager (PBM)*, discussed in section II.C.3. of this proposed rule.
- *PBM function*, discussed in section II.C.3. of this proposed rule.
- *Related service*, discussed in section II.C.3. of this proposed rule.
- *Remuneration*, discussed in section II.C.6. of this proposed rule.

3. Pharmacy Benefit Manager (PBM)

Section 1860D–12(h)(7)(C) of the Act defines a PBM as “any person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a PDP sponsor or prescription drug plan, or manages the prescription drug benefits provided by such sponsor or plan, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered Part D drugs, or the provision of related services. Such term includes any person or entity that carries out one or more of the activities described in the preceding sentence, irrespective of whether such person or entity calls itself a ‘pharmacy benefit manager.’”

This definition is functional in nature. An entity may qualify as a PBM based on the activities it performs, regardless of how it describes itself. The Act identifies the functions of a PBM as including the processing and payment of prescription drug claims, drug utilization review, processing of prior authorization requests, adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered Part D drugs, and the provision of related services, but does not limit the scope of the PBM definition to the persons and entities that engage in those activities. In addition, a person or entity may qualify as a PBM even if it carries out these functions indirectly through an intermediary.

Determining whether a particular entity is: (1) a PBM; (2) an affiliate as defined in section 1860D–12(h)(7)(A) of the Act and discussed in section II.C.4. of this proposed rule; or (3) neither is necessary to establish the entity’s obligations under section 1860D–12(h) of the Act.

Specifically, a PBM—but not an affiliate—must have a written agreement with the Part D plan sponsor under which the PBM and its affiliates agree to satisfy certain requirements as specified in section 1860D–12(h) of the Act. The PBM—but not its affiliates—also bears responsibility, under its statutorily required contractual arrangement with the Part D plan sponsor, for submitting an annual report to the Part D plan sponsor and the Secretary under section 1860D–12(h)(1)(C)(i) of the Act, as discussed in

section II.C.8. of this proposed rule. Although an affiliate may hold information that must be reported, the affiliate is not responsible for submitting that information directly to the Part D plan sponsor or the Secretary.

The PBM also has audit-related obligations under its contractual arrangement with the Part D plan sponsor, as required by section 1860D–12(h)(1)(D) of the Act. The PBM must allow an annual audit at the request of the Part D plan sponsor and must provide relevant records, data, contracts, and other information requested by the Part D plan sponsor. Although an affiliate’s records may be produced during an audit, the PBM is responsible for providing information held by its affiliates to the Part D plan sponsor.

Under the contractual requirements mandated by section 1860D–12(h)(1)(B)(i) through (iii) of the Act, a PBM is further responsible for defining, interpreting, and applying pricing guarantee and cost-performance terms transparently and consistently; identifying exclusions; and providing WAC-based equivalents when required. These responsibilities are not imposed directly on affiliates.

Finally, pursuant to the contractual requirements mandated by section 1860D–12(h)(1)(A)(vi)(I) of the Act, a PBM must enter into written agreements with its affiliates requiring them to identify and disgorge impermissible remuneration and must attest that it has entered into those agreements.

(i) Contract Requirement

As a threshold matter, an entity qualifies as a PBM under section 1860D–12(h)(7)(C) of the Act if it: (1) directly, or through an intermediary, performs at least one PBM function; and (2) performs that function on behalf of a Part D plan sponsor or prescription drug plan. Separately, section 1860D–12(h)(7)(A) of the Act defines an “affiliate”—with respect to any PBM or Part D plan sponsor—to include any entity that, directly or indirectly, acts as a contractor, principal, or agent to such PBM or Part D plan sponsor insofar as it performs any of the functions described in 1860D–12(h)(7)(C) of the Act.

These two definitions create a potential overlap. Absent clarification, a contractor or agent of a PBM that performs one or more PBM functions could simultaneously be considered to: (1) qualify as a PBM in its own right under subparagraph (C) because it performs PBM functions and the definition captures entities performing even a single such function regardless of

²¹ <https://www.federalregister.gov/documents/2026/06/18/2026-12344/request-for-information-rfi-pharmacy-benefit-manager-compensation-and-data-collection>.

self-identification; and (2) qualify as an affiliate of the contracting PBM under subparagraph (A)(ii) because it is acting as a contractor performing those same functions. For example, based solely on the requirements related to the performance of PBM functions, a third-party claims processor retained by a PBM to process Part D prescription drug claims for a Part D plan sponsor could qualify as a PBM under subparagraph (C) because it performs a PBM function on behalf of a Part D plan sponsor, while also qualifying as an affiliate under subparagraph (A)(ii) because it performs that function as the PBM's contractor.

Section 1860D–12(h)(1) of the Act also establishes a general rule that any contract entered into with a Part D plan sponsor under this part with respect to a prescription drug plan offered by such sponsor must provide that any PBM acting on behalf of such sponsor has a written agreement with the Part D plan sponsor under which the PBM agrees to certain requirements as specified in section 1860D–12(h) of the Act.

Based on this statutory structure, we propose to clarify that an entity qualifies as a PBM only if it holds a written agreement with a Part D plan sponsor, either directly or through a parent organization of such Part D plan sponsor. We believe this clarification resolves the definitional overlap between PBMs and their affiliates and is consistent with the Act's requirement of a contractual relationship between a PBM and a Part D plan sponsor. We intend that this proposed requirement for a written agreement between a PBM and the Part D plan sponsor can be met by an agreement between the PBM and the parent organization of the Part D plan sponsor to account for instances in which the parent organization possesses delegated contracting authority for subsidiary Part D plan sponsors. We note that our proposal to allow for a Part D plan sponsor to meet its obligation to have a written agreement under section 1860D–12(h)(1) of the Act through its parent organization is consistent with the implementation of section 1860D–12(b)(1) of the Act, under which a Part D plan sponsor may also meet its contract requirements through a written agreement by its parent organization when the parent organization has a legally enforceable delegation of Part D plan sponsor's contracting authority (see, for example, 42 CFR 423.503(a)(3) and 423.504(b)(8)).

Accordingly, we propose to establish at 42 CFR 2804(a) a general rule for PBM status. An entity would qualify as a PBM, regardless of how it describes itself, if: (1) the entity has a written

contract with the Part D plan sponsor, either directly or through a parent organization of such Part D plan sponsor; and (2) the entity, directly or through an intermediary, performs at least one PBM function on behalf of a Part D plan sponsor or prescription drug plan with which it has such written contract.

We solicit comment on this proposal.

(ii) Related Services and PBM Functions

As described earlier in this section, a PBM is any person or entity that acts as a price negotiator or group purchaser on behalf of a Part D plan sponsor or prescription drug plan, or that manages the prescription drug benefits provided by such a sponsor or plan. Section 1860D–12(h)(7)(C) of the Act identifies the functions of a PBM as including the processing and payment of prescription drug claims, drug utilization review, processing of prior authorization requests, adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered Part D drugs, and the provision of related services. Because the Act introduces this list with the word “including” and separately references “the provision of related services,” these enumerated functions are illustrative rather than exhaustive.

To give effect to the “related services” language, CMS considered identifying specific additional functions to treat as PBM functions beyond the six functions enumerated in the statute. That approach would provide certainty, but we believe it could improperly narrow the definition to a fixed list, which would be inconsistent with the statute's broad language. A fixed list could suggest that unlisted functions are excluded, even when they are closely related to the enumerated ones. The Act's use of “including” and its separate reference to “related services” signal that the enumerated functions are illustrative examples. Accordingly, codifying a fixed list of additional functions, however carefully constructed, could be contrary to the statute's open-ended language.

At the same time, we believe “related services” should be defined with sufficient precision to give PBMs and their affiliates compliance parameters given that performing a PBM function on behalf of a Part D plan sponsor or prescription drug plan carries significant regulatory obligations. We believe the best approach is to treat “related services” as services that have a *direct nexus* to the functions enumerated in the statute. This approach would treat the statutory list

as illustrative while still requiring a meaningful connection to those functions.

To provide compliance parameters, we have sought to draw on concepts that are commonly understood to anchor the proposed direct-nexus standard. 42 CFR part 423 does not currently define “price negotiator,” “group purchaser,” “drug benefit management,” “prescription drug benefit management,” or “pharmacy benefit management services” as standalone terms, so no existing overarching definitions are available in the context of the Part D program. However, we propose to use three commonly understood concepts to give the direct-nexus standard an appropriate level of specificity.

First, an “integral part” concept could provide an administrable test for determining when a service is sufficiently connected to an enumerated PBM function to be classified as having a direct nexus to that function—specifically, by asking whether the service is an essential component (that is, “integral part”) of that function's performance. For example, in the context of PBM functions, an entity that performs only one step in adjudicating appeals or grievances may be considered to have not performed “the adjudication of appeals or grievances” as defined in section 1860D–12(h)(7)(C) of the Act. However, that entity may have performed a function that is an “integral part” of appeals or grievance adjudication. However, relying exclusively on this concept would likely be too narrow.

Second a “necessity” standard offers an additional element for operationalizing the direct-nexus approach—capturing not only functions that are components of an enumerated activity but also functions without which an enumerated activity could not reasonably be performed. In the context of PBM functions, this could include, for example, maintaining and operating the data-exchange infrastructure used to transmit claims data for payment processing, prior authorization review, or other purposes. Although maintenance of data-exchange infrastructure is not itself an integral component of the functions enumerated in statute, this maintenance activity could nonetheless be considered necessary to carry out such functions to the extent that payment processing and prior authorization review could not be reliably performed without it.

Third, we believe there is value in including a “support” concept in the definition of direct nexus. Many PBM activities are highly complex and PBMs

sometimes rely on other organizations to perform key elements of those activities to support them. This “support” concept provides a third basis for defining “related services” under the direct-nexus standard—one that extends beyond functions that are a component of, or necessary to, the performance of an enumerated activity to encompass functions that, while not strictly necessary, contribute to the actual operation of those activities. For example, data analysis services—such as producing dashboards, utilization reports, and trend analyses related to cost control, formulary management, or drug utilization review—could be viewed as distinct from the underlying PBM function of controlling the cost of covered Part D drugs in the sense that they are not integral to, or necessary for, carrying out that function. But data analysis may nonetheless support the execution of this function.

Together, we believe these three concepts give the direct-nexus standard the precision and administrability necessary for effective compliance. Accordingly, we propose to define “related service” at 42 CFR 423.2802 as any activity, service, or function that is performed on behalf of a Part D plan sponsor or prescription drug plan and has a direct nexus to the activities that are enumerated in the definition of PBM function and propose that the requisite direct nexus to the enumerated activities will exist if the activity is: (1) integral to such enumerated activity; (2) necessary to carry out such enumerated activity; or (3) performed in support of such enumerated activity. We also propose to define “PBM function” at § 423.2802 to include any activity described in section 1860D–12(h)(7)(C) of the Act inclusive of any related service as we propose to define that term at § 423.2802.

CMS considered including a limiting clause to exclude activities incidentally related to PBM functions but concluded that such a clause would raise concerns similar to those posed by a fixed enumerated list. Moreover, we believe the “related service” definition as proposed would not include activities incidentally related to PBM functions such that a limiting clause would be necessary. Notably, the term “related services” at section 1860D–12(h)(7)(C) of the Act is listed with the enumerated PBM services rather than activities that a PBM or Part D plan sponsor would need to conduct under the ordinary course of business as a company (such as accounting or paying taxes). For example, our proposed definition of “related service” would not include the provision of professional services that,

while necessary to the operations of a PBM, Part D plan sponsor, or prescription drug plan, do not have a direct nexus to the activities that are enumerated in the definition of PBM function. Accounting, auditing, legal, information technology and other professional services that are commonly performed on behalf of any company in the health care industry, but are not related to the enumerated PBM functions, do not become a “related service” that is a PBM function under the proposed definition simply because that service is performed for a PBM, Part D plan sponsor or prescription drug plan. Likewise, we believe the proposed definition of “related service” would not include services by commercial entities that offer information, datasets, technology platforms, or similar products on standardized or generally applicable commercial terms. For example, while information regarding WAC may be necessary to controlling the cost of covered Part D drugs, the sale of data from a drug pricing compendium does not become a “related service” under the proposed definition simply because the purchaser of that data of general applicability is a PBM, Part D plan sponsor or prescription drug plan. If the drug pricing compendium did not perform that data provision service on behalf of a Part D plan sponsor, but rather provided widely commercially available data of general applicability to a variety of customers, the provision of such data would not be considered a “related service” under the proposed definition.

Finally, we note that proposed definition of “related service” describes those services performed on behalf of a Part D plan sponsor or prescription drug plan. Accordingly, provision of information to a PBM, Part D plan sponsor or prescription drug plan by or on behalf of a provider or pharmacy in connection with claims processing, drug utilization review, prior authorization requests or other PBM functions is not itself a PBM function under the proposed definition of “related service.” For instance, a pharmacy services administrative organization (PSAO) performing claims submission on behalf of its client pharmacies would not be performing a PBM function under the proposed definition of related service because the PSAO would be providing the service on behalf of client pharmacies, not the Part D plan sponsor or prescription drug plan.

We solicit comment on this proposal. Specifically, we solicit comment on whether any categories of activities should be explicitly excluded from the

definition of “PBM function” or “related service.”

The definitions of “PBM function” and “related service” at proposed § 423.2802 are intended to ensure that the range of activities that could lead an entity or individual to become a PBM or affiliate for purposes of this rule is clear and comprehensive. We believe the direct-nexus standard in our proposed definition of related service is appropriate to avoid parties understating or circumventing reporting obligations related to *bona fide* PBM functions. As an alternative to the direct-nexus standard in our proposed definition of “related service,” we considered adopting a substantial-similarity standard under which the definition of “related service” would serve as a less prescriptive catch-all to include functions that are different in name but similar in character to the PBM functions provided by a Part D plan sponsor or prescription drug plan that are expressly listed in section 1860D–12(h)(7)(C) of the Act. Specifically, an alternative definition of “related service” could be “an activity, service or function that is substantially similar to a function listed in section 1860D–12(h)(7)(C) of the Act and any successor function to any listed function.” We believe this alternative definition could provide clarity by emphasizing that the scope of a “related service” is coextensive with the activities on behalf of a Part D plan sponsor or prescription drug plan that are acting as a price negotiator or group purchaser on behalf of such sponsor or plan or involve the management of the prescription drug benefits provided by such sponsor or plan. However, we have concern such definition may be underinclusive or insufficiently precise to be administrable. We solicit comment on this alternative definition and whether the direct-nexus standard in our proposal or this substantially similar alternative would define “related service” in a manner that better enables consistent and complete identification of PBM functions for purposes of the reporting obligations under this proposed rule.

(iii) Minimum Threshold for Performance of a PBM Function

As discussed earlier in this section, the PBM definition is functional in nature. An entity may qualify as a PBM based on the activities it performs, regardless of how it describes itself. To determine when PBM status applies based on the performance of a particular PBM function, we must establish whether a minimum level of performance is required—in other

words, whether a single instance of performing a PBM function renders an entity a PBM.

We considered a *de minimis* or safe harbor approach under which CMS would establish numeric thresholds—such as minimum claims volume or dollar value of transactions—below which an entity's performance of a listed function would not trigger PBM status. However, calibrating appropriate thresholds across the full range of PBM functions would be analytically complex and potentially subject to gaming. Moreover, the statute does not specify any minimum frequency, volume, or materiality threshold for PBM function performance. An explicit threshold-based *de minimis* standard would therefore be in tension with the statutory language, which does not contemplate such a carve out.

We also considered a contractual standard, under which PBM status would be determined based on the terms of a written agreement to perform services on behalf of a Part D plan sponsor or prescription drug plan. Under this approach, an entity that has contracted to perform certain functions would be presumed to perform those functions during the contract term. However, actual performance cannot always be derived from contractual terms. A contractual standard therefore risks being simultaneously overinclusive—capturing entities that contracted to perform certain functions but do not actually do so—and underinclusive—failing to capture entities that do perform certain functions not expressly required under a contract.

Instead, we propose to adopt an “any performance standard,” under which PBM status attaches the moment an entity performs even a single instance of any listed PBM function, regardless of frequency, volume, or materiality. We believe this approach is most consistent with the statutory structure, which does not explicitly contemplate limitations on the minimum level of performance required to confer PBM status.

Accordingly, at 42 CFR 423.2804(b), we propose to clarify that an entity satisfies the performance element of the PBM definition upon performing one or more PBM functions during a calendar year, regardless of the frequency, volume, regularity, or materiality of such performance.

We recognize that application of an “any performance standard” could, in some circumstances, be overinclusive. However, we believe that the additional statutory constraints that a PBM function be an act as a price negotiator or group purchaser on behalf of a Part

D plan sponsor or to manage the benefits provided by such sponsor or plan substantially limit the potential for over-inclusiveness. Certain functions that are included in the statutory definition of PBM are routinely performed by entities for purposes unrelated to pharmacy benefit management. For example, pharmacies process prescription drug claims as part of their own operational workflows (for example, when submitting claims to Part D plan sponsors seeking payment), which are independent of any functions they may also carry out on behalf of the Part D plan sponsor. Likewise, pharmacies and pharmacists regularly provide certain clinical services to their patients, such as drug utilization review and medication adherence monitoring, in accordance with applicable state pharmacy practice or professional conduct requirements, respectively, without regard to whether the drug is dispensed to an enrollee of a Part D plan for which the Part D plan sponsor has engaged any person or entity to act as a price negotiator or group purchaser on its behalf or to manage its prescription drug benefit. Accordingly, we believe that the statutory text establishing that an entity performs a PBM function when it acts as a price negotiator or group purchaser *on behalf of* a Part D plan sponsor or prescription drug plan or to manage the benefits *of such sponsor or plan* should substantially limit the potential for over-inclusiveness in understanding which pharmacy and wholesaler activities are PBM functions. Nevertheless, we request comment on whether circumstances exist in which this standard could still be overinclusive, and whether CMS should consider additional limitations.

We request comment on this proposal.

(iv) Intermediaries

The statute includes within the definition of PBM entities that act “through an intermediary” but does not define the term “intermediary,” raising two questions: what constitutes an intermediary, and when does an entity that performs PBM functions through an intermediary qualify as a PBM?

Part D regulations already employ a conceptually similar framework through the “first tier, downstream, and related entity” categories. Under 42 CFR 423.501:

- A first tier entity is “any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.”

- A downstream entity is a “party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first-tier entity,” continuing down to the level of the ultimate provider of health and administrative services.

- A related entity is an entity that is “related to the PDP sponsor by common ownership or control and (1) performs some of the Part D plan sponsor's management functions under contract or delegation; (2) furnishes services to Medicare enrollees under an oral or written agreement; or (3) leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.”

Under 42 CFR 423.505(i), Part D plan sponsors may delegate functions to these entities. Contracts with such entities must preserve audit and record-access rights for HHS, the Comptroller General, and their designees.²² These entity types are further incorporated into compliance program, prescription drug event (PDE) submission, claims-data certification, and Medicare Transaction Facilitator Data Module requirements.²³

There are meaningful similarities between first tier, downstream, and related entities and intermediaries. Both concepts are function-based: first tier, downstream, and related entities are identified, in part, by their performance of administrative or health care services under Part D, while the PBM and intermediary concepts under section 1860D–12(h) of the Act similarly depend on an entity's performance of PBM functions. Both are chain-of-delegation concepts that reach below a direct contractor to downstream entities, and both preserve accountability for compliance obligations notwithstanding outsourcing. The first tier, downstream, and related entity framework preserves sponsor responsibility despite delegation to another entity, which is similar to how the Act imposes PBM status, and associated accountability for compliance with certain requirements as specified in section 1860D–12(h) of the Act, on an entity regardless of whether it uses intermediaries to perform PBM functions.

However, the two concepts are not exact analogs. First tier, downstream, and related entity status is triggered by a written arrangement to provide administrative or health care services under Part D and applies broadly to Part D contractors regardless of whether they

²² See 42 CFR 423.505(i)(2) through (4).

²³ See 42 CFR 423.504(b)(4)(vi)(B), (D), (F); 423.325(a)(1) through (2), (b); 423.505(k), (q).

perform PBM functions. By contrast, intermediary status is not expressly dependent on a written agreement, applies more narrowly within the context of PBM functions, and does not extend to entities performing exclusively non-PBM functions. Therefore, we believe it is appropriate to establish a definition of “intermediary” for purposes of section 1860D–12(h) of the Act that accounts for differences from the standard used to determine first tier, downstream and related entity status.

Given the complexity of modern pharmacy benefit arrangements, which commonly involve multi-layered contractual chains, we believe the definition of “intermediary” and the statutory phrase “through an intermediary” should be interpreted broadly to give appropriate effect to the statute.²⁴ Accordingly, at proposed § 423.2802, we propose to define “intermediary” to mean any person or entity in a chain of contractual or delegated relationships, of any length, through which one or more PBM functions are performed on behalf of a Part D plan sponsor or prescription drug plan during a calendar year. At proposed § 423.2804(c), we would specify that any entity that causes, arranges, procures, or relies on an intermediary to perform a PBM function must be deemed to have performed that function for all purposes of section 1860D–12(h) of the Act.

Under this approach, an entity would qualify as a PBM acting through an intermediary if—

- The entity holds a written contract with the Part D plan sponsor, either directly or through a parent organization of such Part D plan sponsor, to provide or arrange PBM functions;
- The entity causes, arranges, procures, or relies on another entity to perform one or more listed PBM functions on behalf of the Part D plan sponsor or prescription drug plan as described in such written contract; and
- That intermediary performs such function on behalf of such Part D plan sponsor or prescription drug plan.

We considered limiting intermediary status to entities within a set number of links in a contractual chain. However,

that approach would allow entities to shield PBM activities from section 1860D–12(h) of the Act by positioning the function-performing entity far enough from the Part D plan sponsor to fall outside the intermediary definition.

We also considered a control-based approach, under which a PBM acting through an intermediary would be required to direct or control how the function-performing entity performs the PBM function. For example, a PBM could be said to direct or control a function-performing entity when the PBM contracts with a rebate aggregator to negotiate manufacturer rebates on behalf of a Part D plan sponsor, and the PBM sets the negotiation parameters, approves or rejects rebate offers, specifies which manufacturers or drugs the aggregator must prioritize, or requires the aggregator to follow PBM-established formulary or contracting terms. However, that approach would be highly fact-specific and could create significant uncertainty about when PBM status attaches to an entity acting through an intermediary.

We request comment on this proposal and on potential alternative approaches.

(v) Performance of PBM Functions by Part D Plan Sponsors

Section 1860D–12(h)(7)(C) of the Act defines a PBM in part as “any person or entity that . . . acts as a price negotiator or group purchaser on behalf of a prescription drug plan sponsor or prescription drug plan, or manages the prescription drug benefits provided by such sponsor or plan.” Additionally, section 1860D–12(h)(1)(A)(iii) of the Act addresses the application of requirements for agreements with PBMs “in cases where a PDP sponsor is acting as a pharmacy benefit manager on behalf of a prescription drug plan offered by such PDP sponsor.”

Taken together, these provisions could be read to suggest that the requirements of section 1860D–12(h) of the Act apply to all Part D plan sponsors that engage in any activity which we propose to include within the definition of PBM functions under proposed § 423.2802. However, most of the statutory requirements in section 1860D–12(h) of the Act contemplate a two-party relationship between a Part D plan sponsor and a PBM. This raises the question of whether—and under what circumstances—a Part D plan sponsor that performs the activities described in the proposed definition of PBM functions is subject to the requirements of section 1860D–12(h) of the Act.

Under existing Part D statutory and regulatory requirements, a Part D plan sponsor’s contract with CMS must

require the sponsor to, among other things: provide qualified prescription drug coverage; comply with quality assurance and cost and utilization management requirements; support e-prescribing; comply with coverage determination, grievance, appeal, and formulary exception requirements; submit claims and other information to CMS; provide information CMS determines necessary to carry out the applicable payment provisions; and operate systems that adjudicate drug claims at the point of sale.²⁵ The activities described in these requirements for Part D plan sponsors overlap significantly with the activities that are characterized as PBM functions under proposed § 423.2802.

Nevertheless, the overall structure of section 1860D–12(h) of the Act largely assumes that a Part D plan sponsor and a PBM are separate entities and seeks to hold the PBM accountable to the Part D plan sponsor for the PBM’s activities on behalf of the sponsor. For example, section 1860D–12(h)(1)(C)(i) of the Act requires the PBM to submit an annual report to both the Part D plan sponsor and the Secretary. Section 1860D–12(h)(1)(D) of the Act provides a Part D plan sponsor with audit rights over the PBM to ensure the PBM’s compliance with the written agreement and the accuracy of information reported under section 1860D–12(h)(1)(C) of the Act. Likewise, section 1860D–12(h)(2)(A)(ii) of the Act requires that, in order to enforce the requirements related to PBMs, each Part D plan sponsor is required to have a written agreement with any PBM—or an affiliate of such PBM—acting on behalf of such sponsor that requires the PBM or affiliate to reimburse the sponsor for any civil money penalty imposed on the sponsor as a result of the PBM’s or affiliate’s failure to meet applicable requirements. This consistent structural distinction between a PBM and a Part D plan sponsor suggests that a Part D plan sponsor is not a PBM for purposes of section 1860D–12(h) of the Act solely by virtue of its functions as a Part D plan sponsor—even though Part D plan sponsors engage in activities that overlap with the activities in the PBM definition. At the same time, the statute does not categorically exclude Part D plan sponsors from ever qualifying for PBM status. Rather, the overall structure of section 1860D–12(h) of the Act affirms that a Part D plan sponsor is a PBM when it is performing PBM functions on behalf of a distinct entity (that is, when such activities performed

²⁴ The FTC has described PBM-administered pharmacy benefit arrangements as involving multiple interacting layers, including plan sponsors, PBMs, affiliated and unaffiliated pharmacies, post-sale reimbursement adjustments, spread pricing, vertically integrated PBM-pharmacy-insurer entities, and PBM-affiliated rebate aggregators that negotiate with manufacturers. Fed. Trade Comm’n, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers: Second Interim Staff Report* 3–8, 18, 23 (Jan. 2025).

²⁵ See 42 CFR 423.505(b)(4), (b)(6), (b)(7), (b)(8), (b)(9), and (b)(17).

by the Part D plan sponsor are not performed under the sponsor's own contract for the operation of the Part D plan sponsor's own prescription drug plan).

Therefore, we propose to clarify a limitation on how the performance standard to have PBM status as described in proposed § 423.2804(a) applies to the activities of a Part D plan sponsor. Specifically, we propose to establish in proposed § 423.2804(d) that a Part D plan sponsor would not meet the performance standard in paragraph (a)(2) based solely on the sponsor performing activities under such sponsor's contract for the operation of its own prescription drug plan.

We considered supplementing this proposal with regulatory text to identify criteria under which a Part D plan sponsor would meet the performance standard for PBM status as described in proposed § 423.2804. For example, we considered whether to affirm in regulatory text that a Part D sponsor would meet the standard for PBM status in proposed § 423.2804 if the sponsor performs one or more functions described at proposed paragraph § 423.2802 with respect to a prescription drug plan for which it does not have a contract with CMS or if the sponsor or any affiliate of such Part D plan sponsor derives any remuneration from any entity in connection with the sponsor's performance of PBM functions on behalf of a separate Part D plan sponsor. We also considered whether to introduce regulatory text to clarify how the performance standards would apply to a Part D plan sponsor in the context of a vertically integrated entity. However, we concluded that regulatory text to this effect would be superfluous and could inadvertently understate the standards for PBM status as applied to Part D plan sponsors.

Under proposed § 423.2804(d), a Part D plan sponsor would not meet the standards for PBM status based solely on the sponsor performing activities under such sponsor's contract for the operation of its own prescription drug plan; however, this proposal does not limit the circumstances in which a Part D plan sponsor may meet the standards for PBM status based on the sponsor performing activities on behalf of other prescription drug plans. As noted previously, section 1860D–12(h)(1)(A)(iii) of the Act permits manufacturer price concessions, including concessions that are calculated as a percentage of a drug's price, provided they are fully passed through to the Part D plan sponsor and comply with all regulatory and subregulatory requirements related to

DIR, for manufacturer rebates, discounts, and other price concessions. This exception to the otherwise applicable remuneration restrictions on PBMs and their affiliates in section 1860D–12(h)(1)(A) of the Act explicitly encompasses scenarios where a Part D plan sponsor acts as a PBM on behalf of a prescription drug plan it offers. Accordingly, we propose to clarify how this exception applies in the context of a Part D plan sponsor that does not fall within the specific limitation on PBM status described at proposed § 423.2804(d). Specifically, we propose that when assessing whether a price concession complies with the requirements in section 1860D–12(h)(1)(A)(iii) of the Act as described in proposed § 423.2810(d), in cases where the Part D plan sponsor meets the standards for PBM status described at proposed § 423.2804(a)(2) and acts as a PBM on behalf of its own prescription drug plan, a price concession to such sponsor for such plan would be deemed to satisfy the passed through condition in paragraph (d)(2)(i) of this section, provided that such Part D plan sponsor receives 100 percent of the gross economic value of the price concession. This clarification ensures a price concession can meet the requirement that it be fully passed through to the Part D sponsor even in those cases where the price concession is paid to a sponsor acting as a PBM on behalf of its own prescription drug plan. We believe this interpretation best resolves the statutory tensions discussed above by preserving the structural distinction between a PBM and a Part D plan sponsor inherent across the various requirements of section 1860D–12(h) of the Act, while also giving full force to the statute's express directive that rebates, discounts, and other price concessions from manufacturers be fully passed through to the Part D plan sponsor including in cases where the sponsor is acting as a PBM on behalf of its own prescription drug plan.

We request comment on these proposals, including whether this proposed approach to applying PBM status to Part D plan sponsors achieves the appropriate application of transparency and remuneration requirements.

4. Affiliate

Section 1860D–12(h)(7)(A) of the Act defines an affiliate, “with respect to any pharmacy benefit manager or PDP sponsor,” as “any entity that, directly or indirectly—(i) owns or is owned by, controls or is controlled by, or is otherwise related in any ownership structure to such pharmacy benefit

manager or PDP sponsor; or (ii) acts as a contractor, principal, or agent to such pharmacy benefit manager or PDP sponsor, insofar as such contractor, principal, or agent performs any of the functions described under subparagraph (C).”

This definition has two independent prongs: an ownership or control prong, set out in clause (i), and a functional and contractual prong, set out in clause (ii). As the statute sets these prongs out as alternatives, an entity that satisfies either prong qualifies as an affiliate, regardless of whether it satisfies the other.

Determining whether a particular entity is an affiliate is necessary to establish the entity's obligations under section 1860D–12(h) of the Act. As discussed in section II.C.1. of this proposed rule, the PBM industry is characterized by complex affiliate structures and substantial vertical and horizontal integration. In addition, PBMs have demonstrated an ability to adapt to changing legislative and regulatory dynamics. Together, these factors underscore the importance of determining affiliate status for the effective administration of section 1860D–12(h) of the Act.

Although affiliates have fewer obligations under the Act than PBMs, they remain subject to significant requirements. Specifically, affiliates are subject to the same bona fide service fee restrictions as PBMs under section 1860D–12(h)(1)(A) of the Act. Affiliates must also identify and disgorge impermissible remuneration to the PBM under the required PBM-affiliate agreement described in section 1860D–12(h)(1)(A)(vi)(I) of the Act.

In addition, information concerning affiliates is required to be included in the PBM's annual report. This includes information regarding an affiliate's retained revenue, pharmacy activity, acquisition costs, 340B arrangements, compensation paid to consultants or brokers, and identity as an affiliate under sections 1860D–12(h)(1)(C)(i)(I)(kk), (II), (VI), (VIII), (IX), and (X) of the Act.

Information owned or held by an affiliate may also be subject to audit. Under section 1860D–12(h)(1)(D)(v) of the Act, such information must be produced by the PBM if it is required for reporting or audit verification.

Furthermore, manufacturer contracts entered into by affiliates may trigger disclosure obligations. A manufacturer agreement entered into by an affiliate can trigger the written-explanation requirement under section 1860D–12(h)(1)(C)(ii)(I) of the Act if the agreement involves rebates, discounts,

payments, or other financial incentives contingent on coverage, formulary placement, or utilization-management conditions. Under section 1860D–12(h)(1)(C)(ii)(II)(bb) of the Act, an affiliate’s Chief Executive Officer, Chief Financial Officer, or General Counsel or individual delegated the authority to sign on behalf of one of these officers may also be required to certify the explanation when the affiliate is the relevant contracting entity.

Affiliates may also be required to reimburse Part D plan sponsors for certain penalties. Under section 1860D–12(h)(2)(A)(ii) of the Act, a Part D plan sponsor must require an affiliate to reimburse the sponsor for civil money penalties imposed on the sponsor as a result of the affiliate’s failure to meet applicable requirements.

Additionally, affiliates must be subject to punitive contractual remedies. Under section 1860D–12(h)(2)(A)(iii) of the Act, a Part D plan sponsor must require an affiliate to be subject to punitive remedies for breach of contract if the affiliate fails to comply with applicable requirements under the Act.

The affiliate designation is also central to the implementation of the essential retail pharmacies requirements at section 1860D–42(e) of the Act, as added by section 6223(b) of the CAA. Among other requirements, section 1860D–42(e) of the Act directs CMS to publish an annual list of essential retail pharmacies and requires Part D plan sponsors to submit to CMS a list of retail pharmacies that are affiliates of such sponsor or are affiliates of a PBM acting on behalf of such sponsor. Section 1860D–42(e)(4) of the Act provides that the definitions for PBM and affiliate in the provisions implementing section 6224 of the CAA apply to implementation of the essential retail pharmacies requirements under section 1860D–42(e) of the Act. Accordingly, Part D plan sponsors will be using the regulatory standard finalized through this rulemaking when making their annual report of affiliated retail pharmacies, as required by section 1860D–42(e)(3)(B) of the Act. Moreover, because the definition of essential retail pharmacy at section 1860D–42(e)(2)(A) of the Act excludes affiliates, every pharmacy that is an affiliate under proposed § 423.2802 must be excluded from the list of essential retail pharmacies published under 1860D–42(e)(3)(A) of the Act. Acknowledging that this rulemaking does not otherwise address the essential retail pharmacies provisions, we solicit comment on how the affiliate standard being proposed here, if finalized, would impact the

implementation of these essential retail pharmacies provisions, including how sponsors would implement this standard for purposes of their reporting obligations under section 1860D–42(e)(3)(B) of the Act.

Section 1860D–12(h)(7)(A)(i) of the Act defines “affiliate” through three independent clauses: “owns or is owned by,” “controls or is controlled by,” and “otherwise related in any ownership structure.” Each clause is independently sufficient to establish affiliate status, and CMS intends to propose regulations giving effect to each. Given the breadth of this prong, CMS also intends to build on existing concepts of ownership, control, attribution, and aggregation to specify a workable framework to the greatest extent possible.

Several Part D regulatory provisions already establish ownership and control concepts with respect to Part D plan sponsors. We discuss several different Part D regulatory provisions including first tier, downstream and related entities; parent organizations; and Part D party in interest rules. We also discuss ownership and control concepts from other Federal provisions and agencies, including definitions used in the Internal Revenue Code (IRC) controlled group rules, Employee Retirement Income Security Act of 1974 (ERISA) party in interest rules, and Security and Exchange Commission (SEC) beneficial ownership rules.

First tier, downstream, and related entities. As discussed in section II.C.2.a. of this proposed rule, Part D regulations regularly refer to “first tier, downstream, or related entities” together. Under 42 CFR 423.4:

- A first tier entity is “any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.”
- A downstream entity is “any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity,” continuing down to the ultimate provider of health and administrative services.
- A related entity includes an entity “related to the Part D sponsor by common ownership or control” that either (1) performs some of the Part D plan sponsor’s management functions under contract or delegation, (2) furnishes services to Medicare enrollees under an oral or written agreement, or (3) leases real property or sells materials

to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

There are meaningful similarities between the requirements applicable to affiliates under section 1860D–12(h) of the Act and those applicable to first tier, downstream, and related entities under Part D regulations. Under 42 CFR 423.505(i), Part D plan sponsors may delegate functions to such entities. Under 42 CFR 423.505(i)(2) through (4), contracts with those entities must preserve audit and record-access rights for HHS, the Comptroller General, and their designees. First tier, downstream, and related entities are also incorporated into compliance program, PDE submission, claims-data certification, and Medicare Transaction Facilitator Data Module requirements.²⁶

However, these existing concepts are not perfect analogs for affiliates under the ownership and control prong. A first-tier entity must have a direct written arrangement with a Part D plan sponsor; downstream entities sit below that relationship; and related entities are linked to the Part D plan sponsor through common ownership or control and certain service, property, or management relationships. The ownership and control prong of section 1860D–12(h)(7)(A)(i) of the Act, by contrast, captures entities that own or are owned by the PBM or Part D plan sponsor without regard to the entity’s position in the Part D contract chain. The existing ‘related entity’ definition does capture entities connected to a Part D plan sponsor by common ownership or control. However, it also imposes additional functional requirements—namely that the entity perform management functions or furnish services to enrollees—that are not present in the affiliate definition’s ownership and control prong.

Parent organizations. Under 42 CFR 423.4, a “parent organization” is the legal entity that exercises a controlling interest through share ownership, the power to appoint voting board members, or other means, directly or through subsidiaries. “Parent organization” is used in various contexts to determine when legally separate entities or contracts should be treated as related for Part D regulatory purposes. For example, the term is used to determine when contracts or plans are sufficiently related to permit consolidation, crosswalks between plan benefit packages (PBPs), or transfers between wholly owned subsidiaries of the same parent organization. Section 423.182(a)

²⁶ See 42 CFR 423.504(b)(4)(vi)(B), (D), (F); 423.325(a)(1)–(2), (b); 423.505(k); 423.505(q).

defines consolidation by reference to contracts under the same parent organization. Sections 423.530(a)(2)(i) and 423.530(c)(2)(i) address crosswalks involving contracts or plans under the same parent organization. Section 423.551(g)(1) recognizes certain transfers between wholly owned subsidiaries of the same parent organization.

The definition shares important features with the ownership and control prong—both contemplate multi-tier ownership chains and non-ownership-based arrangements that confer control. However, under the existing parent organization definition, ownership and control are intertwined, whereas the affiliate definition treats ownership and control as distinct and independently sufficient bases for affiliate status.

Under the parent organization definition, shared ownership may establish a “controlling interest.” In that context, ownership can be the mechanism by which control is established. By contrast, the affiliate definition treats ownership and control as distinct, alternative bases for affiliate status. An entity may qualify as an affiliate if it “owns or is owned by” another entity, “controls or is controlled by” another entity, or is otherwise related through an ownership structure.

Part D Party in Interest Rules. Under 42 CFR 423.501, a “party in interest” includes, among other categories, any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization’s equity, or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization. The definition therefore includes a clear ownership-based threshold, but it is not limited to ownership interests. It also includes certain management or administrative personnel, nonprofit incorporators or members, related entities, persons or entities under common control with the Part D plan sponsor, and certain family members.

The Part D requirements applicable to parties in interest are more limited than the requirements applicable to affiliates. Under 42 CFR 423.514(b)(1), a Part D plan sponsor must annually report to CMS significant business transactions with parties in interest and must either indicate that the transaction costs do not exceed the costs that would have been incurred in comparable transactions with persons who are not parties in interest or justify any higher costs as consistent with prudent management and fiscal soundness requirements. Under 42 CFR 423.514(b)(2), a Part D plan sponsor must submit a combined

financial statement for itself and a party in interest if either 35 percent or more of the Part D plan sponsor’s operating costs go to a party in interest, or 35 percent or more of the revenue of a party in interest is from the Part D plan sponsor. Under 42 CFR 423.514(c), the combined financial statements must separately present the financial information for the sponsor and each party in interest, eliminate inter-entity transactions in the consolidated column, and be examined by an independent auditor in accordance with generally accepted accounting principles, with appropriate opinions and notes.

Affiliates, on the other hand, are subject to broad remuneration restrictions and reporting requirements. Accordingly, we believe the 5-percent beneficial ownership threshold used to identify certain parties in interest is not appropriate for identifying affiliates, as it would impose significant compliance obligations on a broad swath of entities which may have limited relationships with Part D plan sponsors and PBMs.

Beyond CMS’s own precedents, several other federal regulatory and statutory frameworks address concepts of ownership and control.

IRC controlled group rules. The IRC’s controlled group rules represent a well-developed framework for determining when separate entities are treated as a single economic unit. Section 1563 of the IRC defines “controlled group of corporations” and identifies three types:

- A parent-subsidiary group, consisting of one or more chains of corporations connected through stock ownership of a common parent. That is, to have a parent-subsidiary group, a common parent must own at least 80 percent of the voting power or value of at least one subsidiary member, and 80 percent of the voting power or value of every other subsidiary member is owned by another subsidiary member of the group (§ 1563(a)(1));

- A brother-sister group, consisting of two or more corporations in which five or fewer individuals, estates, or trusts own at least 80 percent of each corporation and share more than 50 percent identical ownership of each corporation (§ 1563(a)(2) and (f)(5)); and

- A combined group consisting of three or more corporations that, together, form a hybrid of the parent-subsidiary and brother-sister structures, with one of the corporations being both the common parent of a parent-subsidiary group and a member of a brother-sister group (§ 1563(a)(3) of the IRC).

Section 1563 of the IRC also provides detailed constructive ownership rules—

including family and entity attribution under section 1563(d) through (e) of the IRC—ensuring that control is measured based on both direct and indirect interests, as well as through options.

The IRC also contains related aggregation provisions that identify controlled groups or commonly controlled trades or businesses for different regulatory purposes. Section 414(b) and (c) of the IRC treat employees of controlled groups of corporations and trades or businesses under common control as employed by a single employer for specified employee benefit plan provisions of the Code, using the section 1563(a) of the IRC definitions and 80-percent controlled group standard with modifications for corporate controlled groups and parallel regulatory rules for trades or businesses under common control. ERISA Title IV separately uses section 414 of the IRC concepts in Pension Benefit Guaranty Corporation regulations.²⁷ Section 52 of the IRC likewise aggregates employees of controlled groups of corporations and trades or businesses under common control for purposes of the work opportunity credit and expressly substitutes “more than 50 percent” for “at least 80 percent” in section 1563(a)(1). As a result, § 52 may aggregate a broader set of entities than the baseline section 1563(a) of the IRC 80-percent controlled group standard used in Section 414(b) through (c) of the IRC. Section 52 of the IRC is also incorporated into Medicare Part D through section 1860D–14C(g)(4) of the Act, which treats all persons treated as a single employer under section 52(a) or (b) of the IRC as one manufacturer for purposes of the “specified manufacturer” and “specified small manufacturer” phase-in rules.

The IRC controlled group frameworks align with the affiliate definition in several respects. They directly address direct ownership, indirect ownership through attribution, and control via equity interests—all concepts that map closely to the statutory language “directly or indirectly owns or is owned by, controls or is controlled by.” They incorporate constructive ownership, including family attribution and ownership through entities which supports the statutory requirement to capture indirect ownership relationships.²⁸ And they explicitly define parent-subsidiary chains and brother-sister common ownership structures.

However, the IRC aggregation frameworks have limitations in this

²⁷ See 29 CFR 4001.2 “Controlled group.”

²⁸ Section 1563(d), (e) of the IRC.

context. For corporate controlled groups, the rules define control by reference to stock ownership and the relative voting power and value of the owned stock.²⁹ They therefore may not capture all forms of practical control relevant to 1860D–12(h) of the Act, for example, whether and to what extent economic dependence standing alone affects the determination of stock ownership or voting power. Of the IRC controlled group provisions, overall, subsections (a) and (b) of section 52 of the IRC are best aligned with the objectives of section 1860D–12(h) of the Act. Section 52 is designed to prevent businesses under common economic control from multiplying tax benefits by operating through separate entities—a concern similar to section 1860D–12(h)’s of the Act aim of extending remuneration restrictions to affiliates in common ownership or control arrangements.

ERISA party in interest rules. Section 3(14) of ERISA defines a “party in interest” with respect to an employee benefit plan, and absent an exemption, Section 406 of ERISA prohibits employee benefit plans from entering into certain transactions with parties in interest because they may be positioned to exercise improper influence over the employee benefit plan.³⁰ A party in interest includes, among other categories, direct or indirect owners of 50 percent or more of the combined voting power or total value of a corporation, the capital or profits interest of a partnership, or the beneficial interest of a trust or unincorporated enterprise that is an employer or employee organization whose employees or members are covered under the employee benefit plan. . . .³¹ The definition also includes entities in which 50 percent or more of those interests are owned or held by certain other parties in interest.³² Like the IRC controlled group frameworks discussed previously, these ERISA provisions ground certain affiliation rules in voting power, share value, capital or profits interests, and beneficial interests.³³ However, section 3(14)(I) of ERISA also captures a 10-percent-or-more partner or joint venturer, measured directly or indirectly by capital or profits, of a person described in certain other party-in-interest categories, offering a

potential analogue for addressing joint-venture interests in the PBM context.

Security and Exchange Commission (SEC) beneficial ownership rules. The SEC’s beneficial ownership framework under Exchange Act Regulation 13D–G provides a governance-focused analog for identifying ownership arrangements that may convey voting or investment control without majority equity ownership.³⁴ Under 17 CFR 240.13d–3(a), a person is the beneficial owner of a security if that person, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise, has or shares voting power, including the power to vote or direct the voting of the security, or investment power, including the power to dispose or direct the disposition of the security.³⁵ Beneficial ownership is therefore not limited to formal record ownership and may arise through contractual, relational, or other indirect mechanisms.³⁶ Under 17 CFR 240.13d–3(b), a person may not avoid beneficial ownership by using a trust, proxy, power of attorney, pooling arrangement, or other contract, arrangement, or device as part of a plan or scheme to evade the reporting requirements of sections 13(d) or 13(g) of the Securities Exchange Act of 1934.³⁷ In addition, persons that beneficially own more than 5 percent of a covered class of equity securities generally must report that ownership, and the “purpose or effect” of changing or influencing the control of the issuer is one key condition bearing on whether certain filers may report on Schedule 13G rather than Schedule 13D.³⁸

We recognize that this analysis is not an exhaustive survey of existing frameworks and welcome comment on other frameworks or principles that CMS should consider.

Principles Derived from Existing Frameworks. Several common principles emerge from the foregoing analysis and inform the proposed regulatory framework:

- **Entity-form neutrality.** The regulatory framework should account for corporations, partnerships, limited liability companies, trusts, and other organizational forms so that ownership and control are evaluated consistently across entity types.

- **Attribution rules.** Ownership and control should be attributed to entities that exercise ownership or control through intermediary entities,

consistent with frameworks that recognize indirect ownership, constructive ownership, and beneficial ownership.

- **Governance-based control** independent of equity. Governance rights, including board appointment rights, management rights, consent rights, or veto rights over material decisions, may confer control even without majority equity. Exclusive dealing arrangements or economic dependence may also be relevant where they give one entity practical authority over another entity’s material business decisions.

- **Purpose-or-effect analysis.** For arrangements below any bright-line ownership threshold, CMS could consider whether the arrangement has the purpose or effect of giving one entity the ability to influence material business decisions of another entity.

Accordingly, at 42 CFR 423.2806(a)(1) we propose to establish a general rule that an entity is an affiliate if it satisfies one or more of the following paragraphs.

At proposed paragraph (2), we propose to define an ownership relationship for purposes of section 1860D–12(h) of the Act as one where an entity has an ownership relationship with a PBM or Part D plan sponsor if the entity and the PBM or Part D plan sponsor would be treated as members of a parent-subsidiary controlled group under section 1563(a)(1) of the IRC, as modified by section 52(a), of the IRC, as applicable, including the modifications and attribution rules incorporated or applied under those provisions. We believe these parent-subsidiary controlled group rules provide an appropriate basis for determining majority ownership. Section 52 of the IRC is already incorporated into Part D to aggregate entities when determining manufacturer status, and it captures both direct majority ownership and indirect ownership through chains of entities.

At proposed paragraph (3), we propose to define a control relationship between an entity and a PBM or Part D plan sponsor as one where either the entity or the PBM or Part D plan sponsor has the power to materially determine or direct the material actions, policies, or decisions of the other entity, regardless of ownership percentage, through any of the following: (i) the power to appoint, elect, or remove a majority of the other’s governing body; (ii) contractual veto, consent, or supermajority rights over material business decisions of the other; (iii) contractual rights to appoint, direct, or remove senior officers or to direct day-to-day operations through a

²⁹ Section 52(a), 1563(a) of the IRC.

³⁰ Section 3(14), 406 of ERISA.

³¹ Section 3(14)(E) of ERISA.

³² Section 3(14)(G) of ERISA.

³³ Section 3(14)(E), (G) of ERISA.

³⁴ 17 CFR 240.13d–1, 240.13d–3.

³⁵ 17 CFR 240.13d–3(a)(1), (2).

³⁶ 17 CFR 240.13d–3(a), (c).

³⁷ 17 CFR. 240.13d–3(b).

³⁸ See 17 CFR 240.13d–1(a), (b)(1)(i), (c), (e).

management or administrative services agreement; or (iv) exclusive dealing, requirements contracts, or similar arrangements that, alone or together with other contractual or economic arrangements, give one entity practical authority to direct or materially constrain the other entity's material business decisions related to the Part D program. We also propose that control include indirect control exercised through one or more intermediary entities, assessed link by link through the chain of relationships.

We believe this proposed definition is consistent with existing Part D precedent. Under 42 CFR 423.4, "parent organization" is already defined to mean the legal entity that exercises "a controlling interest, through . . . the power to appoint voting board members, or other means," expressly recognizing governance-based control, independent of equity ownership, as sufficient to establish a control relationship. It is also consistent with the SEC's beneficial ownership framework at 17 CFR 240.13d-3(a), which grounds ownership and control in the practical ability to vote, direct the voting of, or dispose of securities.

At proposed paragraph (a)(4), we propose to define an entity as being otherwise related in an ownership structure to a PBM or Part D plan sponsor if it does not meet the requirements of paragraphs (2) or (3), but the relationship between the entity and a PBM or Part D plan sponsor meets any of the requirements (i) through (iii) described later in this section and the relationship confers meaningful influence either to the entity or to the PBM or Part D plan sponsor: (i) the entities are in a brother-sister controlled group under section 1563(a)(2) of the IRC, as modified by section 52(a) of the IRC; (ii) one entity holds a 10 percent or greater capital or profits interest in a joint venture, limited partnership, limited liability company, or comparable arrangement in which the other participates; or (iii) the totality of the structural features of the relationship confers meaningful influence by one entity over the other, notwithstanding the failure to satisfy the thresholds in paragraphs (a)(4)(i) through (ii). In determining whether the relationship between the entity and the PBM or Part D plan sponsor confers meaningful influence by one entity over the other under paragraph (a)(4), consideration should be given to the purpose or effect of the relationship; financial interdependence; common personnel exercising authority over business decisions; and structural

features indicating evasion of applicable thresholds.

We believe this approach is consistent with existing frameworks for identifying non-majority ownership relationships. For example, section 3(14)(I) of ERISA expressly designates as a "party in interest" any 10 percent or more partner or joint venturer of a person described in other party-in-interest categories, providing precedent for addressing joint venture relationships. In addition, the SEC's Regulation 13D-G distinguishes passive investment from control-seeking investment based on whether the holding was acquired or is held "with the purpose or effect of changing or influencing the control of the issuer," providing precedent for a facts-and-circumstances residual test. Finally, at proposed paragraph (a)(5), we propose that the following principles apply to paragraphs (a)(2) through (4): (i) Entity-form neutrality. "Interest" would be measured by voting power or equity value for corporations; capital or profits interest for partnerships and LLCs; and beneficial interest for trusts and unincorporated enterprises. (ii) Right-to-acquire rules. The right to acquire an ownership interest exercisable within 60 days—through option, warrant, conversion, or revocable proxy—would be treated as a present holding of that interest.

We intend that in the context of vertically integrated structures, the potential affiliation of an entity under this proposal would be assessed based on that particular entity's relationship to the PBM or Part D plan sponsor. If an entity is part of the same vertically integrated structure as a PBM or Part D plan sponsor, then we intend for that entity to be an affiliate of that PBM or Part D plan sponsor as described at § 423.2806(a)(2). If an entity is not part of the same vertically integrated structure as a PBM or Part D plan sponsor, then we intend that the entity would not be an affiliate of the PBM or Part D plan sponsor in the vertically integrated structure unless that entity has a direct relationship with that PBM or Part D plan sponsor and meets the affiliate criteria as described at § 423.2806(a)(3) and (4). We do not intend that affiliation with an entity that is in a vertically integrated structure with a PBM or Part D plan sponsor would confer affiliation with such PBM or Part D plan sponsor, absent a direct relationship with that PBM or Part D plan sponsor that meets the affiliation criteria described at § 423.2806.

We solicit comment on these proposals.

(ii) Functional and Contractual Prong

The functional and contractual prong, set out in the second clause of the affiliate definition, encompasses any entity that acts as a contractor, principal, or agent to a PBM or Part D plan sponsor, "insofar as" that contractor, principal, or agent performs any PBM function.

Unlike the ownership or control prong, which applies categorically to any entity meeting certain relational requirements, the functional and contractual prong conditions affiliate status on an entity's actual performance of PBM functions. The PBM definition is similarly functional, conditioning PBM status on the performance of PBM functions. However, affiliate status under the functional and contractual prong attaches when an entity "acts as a contractor, principal, or agent to such PBM or PDP sponsor, *insofar as* such contractor, principal, or agent performs any of the functions described under subparagraph (C)" (emphasis added).

To determine when affiliate status attaches under the functional and contractual prong, we propose to clarify the effect of the "insofar as" language. We considered several interpretive approaches.

First, we considered a purposive approach under which affiliate status would attach only when performing one or more PBM functions constitutes the primary role under the relevant contract. However, this approach, risks excluding entities retained for multiple purposes where PBM functions represent a substantial—though not primary—component of the contractual relationship. Therefore, we believe this approach would be underinclusive.

Second, we considered establishing quantitative thresholds—such as minimum claims volume or dollar value of transactions—below which an entity's performance of a listed function would not trigger affiliate status. However, calibrating appropriate thresholds across the full range of PBM functions would be analytically complex, and this approach would be susceptible to manipulation through contractual arrangements deliberately structured to fall below any imposed threshold.

Third, we considered applying the same "any performance standard" we are proposing for PBM status. However, this approach, would fail to give effect to the "insofar as" language in the functional and contractual prong, which has no equivalent in the PBM definition. We also believe this approach could be overinclusive, categorizing entities as

affiliates even when they perform PBM functions solely on an incidental basis.

Finally, we considered and elected to propose to codify at proposed § 423.2806(b) that affiliate status attaches under the functional and contractual prong where a contractor, principal, or agent performs one or more PBM functions as a material part of its contractual services. We believe this standard appropriately captures entities for which PBM functions constitute a significant portion of their contractual obligations, without sweeping in entities that perform such functions only incidentally or excluding entities for which such functions are a major—but not primary—part of their contractual obligations.

We solicit comment on this proposal.

5. Part D Plan Sponsor Contracts

Section 1860D–12(h)(1) of the Act requires that, for plan years beginning on or after January 1, 2028, each contract entered into with a Part D plan sponsor under Part D with respect to a prescription drug plan offered by such sponsor must provide that any PBM acting on behalf of such sponsor has a written agreement, acceptable to CMS, with the Part D plan sponsor under which the PBM, and any affiliates of such PBM, as applicable, agree to meet the requirements described in 1860D–12(h)(1)(A) through (D) of the Act. We propose to codify this requirement at §§ 423.2808 and 423.505(b)(28).

Consistent with our authority under sections 1860D–12(b)(3)(D) and (h)(1) of the Act, we propose and further describe the requirements that must be included in the written agreement between the Part D plan sponsor and the PBM acting on behalf of such sponsor in sections II.C.6 through 10. of this proposed rule, and sections II.C.11.b. and c. of this proposed rule, as well as in §§ 423.2810, 423.2812, 423.2814, 423.2816, 423.2818, and 423.2820(b) and (c).

6. Remuneration Requirements

a. Bona Fide Service Fees

Section 1860D–12(h)(1)(A)(i) of the Act, as added by the CAA, requires that PBMs and any affiliates of such PBMs shall not derive any remuneration with respect to any services provided on behalf of any entity or individual, in connection with the utilization of covered Part D drugs, from any such entity or individual other than bona fide service fees, defined in added section 1860D–12(h)(7)(B) of the Act, subject to clauses in section 1860D–12(h)(1)(A)(ii) and (iii) of the Act. This requirement to limit remuneration to bona fide service

fees addresses concerns that PBM practices such as spread pricing or rebate retention may contribute to higher drug costs³⁹ by prohibiting income other than flat dollar amounts for specific, itemized services. Additionally, this requirement addresses concerns that even administrative fee structures (as opposed to spread pricing or rebate retention) create incentives for PBMs to favor higher cost drugs when the administrative fees are based on a percent of the cost of the drug⁴⁰ by prohibiting bona fide service fees from being directly or indirectly based on, or contingent on, drug price.

We are proposing to codify at § 423.2810(b) the statutory requirement that a bona fide service fee be defined as a fee that is reflective of the fair market value (defined at § 423.2802(c)) for a bona fide, itemized service actually performed on behalf of an entity, that the entity would otherwise perform (or contract for) in the absence of the service arrangement and that is not passed on in whole or in part to a client or customer, whether or not the entity takes title to the drug. Such fee must be a flat dollar amount and shall not be directly or indirectly based on or contingent upon—drug price (such as wholesale acquisition cost) or drug benchmark price (such as average wholesale price); the amount of discounts, rebates, fees, or other direct or indirect remuneration with respect to covered Part D drugs dispensed to enrollees in a prescription drug plan, except as permitted under the definition of incentive payments at proposed § 423.2802; coverage or formulary placement decisions or the volume or value of any referrals or business generated between the parties to the arrangement; or the amounts or methodologies prohibited at proposed § 423.2810(b)(3).

(1) Remuneration

Section 1860D–12(h)(1)(A)(i) of the Act sets out a general rule that a PBM and any affiliate of a PBM “shall not derive any remuneration with respect to any services provided on behalf of any entity or individual, in connection with the utilization of covered Part D drugs, from any such entity or individual other than bona fide service fees. . . .”

³⁹ <https://pmc.ncbi.nlm.nih.gov/articles/PMC11482839/>; <https://www.commonwealthfund.org/publications/explainer/2025/mar/what-pharmacy-benefit-managers-do-how-they-contribute-drug-spending>; <https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/>.
⁴⁰ <https://academic.oup.com/healthaffairs/scholar/article/3/7/qxaf126/8173270?login=true>.

This statutory provision has two operative components. First, “remuneration” determines which payment streams are subject to the prohibition. Second, “in connection with covered Part D drug utilization” determines when the restriction applies. Together, these components define the universe of PBM and affiliate remuneration subject to the bona fide service fee restrictions under 1860D–12(h) of the Act.

To determine which payment streams are subject to the general prohibition, we must first understand the meaning of “remuneration” in the context of section 1860D–12(h) of the Act. The statutory structure provides several contextual clues.

First, section 1860D–12(h)(1)(A)(i) of the Act uses the phrase “any remuneration” rather than a narrower term such as “fees,” “payments,” or “compensation.”

Second, section 1860D–12(h)(1)(A)(iii) of the Act creates a specific exception to the prohibition for manufacturer rebates, discounts, and other price concessions under certain conditions. That exception would be unnecessary if such payments were not otherwise encompassed within the general category of remuneration.

Third, section 1860D–12(h)(4) of the Act sets out a rule of construction providing that nothing in section 1860D–12(h) of the Act shall be construed as: (A) prohibiting flat dispensing fees or reimbursement or payment for ingredient costs—including customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers—to entities that acquire or dispense prescription drugs; or (B) modifying regulatory requirements or subregulatory program instructions or guidance related to pharmacy payment, reimbursement, or dispensing fees. This rule of construction would similarly be unnecessary if such payments did not otherwise fall within the general category of remuneration.

Given this statutory structure, we believe “remuneration” must be understood broadly for purposes of section 1860D–12(h) of the Act. Several Part D regulatory provisions, as well as related statutory and regulatory frameworks, already establish concepts of remuneration with respect to services provided in connection with the utilization of Part D drugs, and these provide valuable precedent for specifying the scope of remuneration in this context.

The new statutory provisions cite some of these concepts. For example, the exception for manufacturer rebates,

discounts, and other price concessions at section 1860D–12(h)(1)(A)(iii) of the Act imposes two conditions: (1) the rebates, discounts, and other price concessions must be fully passed through to the Part D plan sponsor, and (2) they must comply with all regulatory and subregulatory requirements related to DIR for manufacturer rebates, discounts, and other price concessions.

CMS has defined several concepts related to remuneration in the context of DIR that are relevant here; the exception for price concessions depends in part on compliance with these existing DIR-related regulatory requirements.

Under 42 CFR 423.308, costs are “actually paid” only if they are actually incurred by the Part D plan sponsor and are net of any DIR—including “discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits”—from manufacturers, pharmacies, enrollees, or any other person that would serve to decrease costs incurred under the Part D plan. Under this provision, remuneration may be direct or indirect, encompass both cash and non-cash value, and include rebates, discounts, price concessions, chargebacks, coupons, grants, and similar benefits.

The definition of “price concession” at 42 CFR 423.100 further supports a broad interpretation of the concept of remuneration. That provision defines a price concession as any form of discount, direct or indirect subsidy, or rebate received by the Part D plan sponsor or its intermediary contracting organization from any source that serves to decrease costs incurred under the Part D plan. It includes discounts, chargebacks, rebates, cash discounts, free goods contingent on purchase agreements, coupons, free or reduced-price services, goods in kind, and other similar benefits—as well as credits, offsets, non-cash benefits, in-kind benefits, and similar direct or indirect financial advantages. Under the statutory structure of section 1860D–12(h) of the Act, such payments would constitute remuneration if the requirements of section 1860D–12(h)(1)(A)(iii) of the Act are not satisfied.

While the provisions discussed previously illustrate the breadth of payments encompassed by “remuneration” for purposes of section 1860D–12(h) of the Act, other statutory frameworks governing remuneration in connection with Part D drug utilization offer precedent for the outer limits of the term.

Specifically, under section 1128B(b) of the Act, the Anti-Kickback Statute (AKS) prohibits knowingly and willfully soliciting, receiving, offering, or paying “any remuneration”—including any kickback, bribe, or rebate—directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce referrals, purchases, leases, orders, or recommendations involving items or services payable by a Federal health care program. The OIG has consistently interpreted “any remuneration” in the AKS context to mean “anything of value.”

Although the regulatory contexts of the AKS and section 1860D–12(h) of the Act differ, both statutes use the same phrase—“any remuneration”—to describe the payments subject to their respective restrictions. Accordingly, we believe it is reasonable to define the outer boundaries of “remuneration” for purposes of section 1860D–12(h) of the Act consistently with the AKS.

Therefore, we propose to define “remuneration” at 42 CFR 423.2802 to mean anything of value, whether provided directly or indirectly, overtly or covertly, in cash or in kind, including, but not limited to, monetary payments, non-cash consideration, administrative fees, data fees, service fees, spread pricing, retained margins, rebates, discounts, chargebacks, price concessions, credits, offsets, up-front payments, coupons, free or reduced-price goods or services, goods in kind, grants, in-kind benefits, guarantee reconciliation amounts, interest payments, financing benefits, and any other direct or indirect financial advantage.

(2) A Service That the Entity “Would Otherwise Perform, or Contract For”

Section 1860D–12(h)(7)(B) of the Act states that a bona fide service fee must be “for a bona fide, itemized service actually performed on behalf of an entity, that the entity would otherwise perform (or contract for) in the absence of the service arrangement.” As discussed in section II.C.6.a. of this proposed rule, we are proposing to define a bona fide service fee as a fee for a bona fide, itemized service actually performed on behalf of an entity, that the entity would otherwise perform, or contract for, in the absence of the service arrangement.

This proposed definition would establish that a fee paid to a PBM will not qualify as a bona fide service fee unless certain conditions are met. To qualify as a bona fide service fee, the underlying service must be one that the entity on whose behalf the service is performed would itself perform, or

procure through a third-party contract, absent the service arrangement. The “would otherwise perform, or contract for” requirement helps to distinguish legitimate service fees from fees that have no meaningful connection to the purchaser’s actual operational needs (such as a data portal fee). To ensure that bona fide service fees reflect genuine value exchanged for real services tied to the entity’s operational needs, we are proposing to establish a regulatory standard for determining when a service qualifies as a “service that the entity would otherwise perform, or contract for.” Absent such a standard, the bona fide service fee framework could potentially be circumvented through arrangements in which fees are nominally labeled as service fees but are for activities that the entity would not otherwise perform.

To define what constitutes a service that an entity would otherwise perform or contract for, and to establish how we would evaluate whether a particular service meets that standard, we considered definitions previously contemplated in rulemaking, including the Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007 (“CY 2007 PFS”). The CY 2007 PFS final rule established that, beginning with average sales price (ASP) reporting for sales during the first quarter of CY 2007, bona fide service fees that are paid by a manufacturer to an entity, whether or not the entity takes title to the drug, are not considered price concessions under § 414.804(a)(2) insofar as, and to the extent that, they satisfy the definition of a bona fide service fee described at § 414.802: “fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement [. . .].”

The CY 2007 PFS explained that these elements of the definition of bona fide service fees established at § 414.802 “encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs.” While this existing definition addresses the concept from the manufacturer’s perspective, the concept that a qualifying service must reflect a

reasonably necessary or useful service of value associated with the efficient distribution of drugs to the entity on whose behalf it is performed is equally appropriate in the context of services performed by a PBM (or other entity) on behalf of Part D plan sponsors.

Therefore, we are proposing a definition of “a service that the entity would otherwise perform, or contract for” that largely aligns with the definition and interpretation of this concept in the CY 2007 PFS final rule, with some additional specifications.

Importantly, there is a distinction between the PBM function performance standard proposed at section 423.2804(b) and the “would otherwise perform, or contract for” requirement. As discussed in section II.C.3. of this proposed rule, under the Act, a PBM is any person or entity that (1) acts as a price negotiator or group purchaser on behalf of a Part D plan sponsor or prescription drug plan; or (2) manages the prescription drug benefits provided by such a sponsor or plan. The Act states that management of prescription drug benefits includes the processing and payment of prescription drug claims, drug utilization review, processing of prior authorization requests, adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered Part D drugs, and the provision of related services, but does not limit prescription drug benefit management to these activities.

This illustrative list of PBM functions enumerated in the statute is relevant to, but not determinative of, whether a particular service for which the entity is paying remuneration to the PBM is one that an entity would otherwise perform or contract for in the absence of a service arrangement with a PBM. Although there will often be substantial overlap between PBM functions and services that an entity would otherwise perform or contract for, the two concepts are distinct, and satisfying one does not necessarily satisfy the other. The fact that a service may be one an entity would otherwise perform or contract for does not itself determine PBM status, which is dependent on the performance of specific PBM functions, as proposed at § 423.2804(b).

To further clarify this distinction between the PBM function performance standard proposed at section 423.2804(b) and the “would otherwise perform, or contract for” requirement of the proposed bona fide service fees definition proposed here, the PBM function performance standard is a threshold that identifies when a person

or entity is performing a PBM function, as defined at proposed § 423.2802 and as discussed in section II.C.3. of this proposed rule. By contrast, the “would otherwise perform, or contract for” requirement proposed here is a separate payment-eligibility standard within the proposed bona fide service fee definition. Relevant to this standard is whether the service for which the fee is paid is a service of operational, administrative, clinical, financial, compliance, or programmatic value to the entity on whose behalf the service is performed, such that the entity would reasonably perform the service itself or procure it from another party in the absence of the service arrangement.

We propose to establish at § 423.2810(b)(2) that a service qualifies as “a service that the entity would otherwise perform, or contract for” if the service is a necessary or useful service of operational, administrative, clinical, financial, compliance, or programmatic value to the entity on whose behalf the service is performed, such that the entity would perform the service itself or procure it from another party in the absence of the service arrangement. We seek comment on this proposed definition and whether additional guidance or examples would be useful to illustrate the application of this payment-eligibility standard within the bona-fide service fee definition to specific types of services commonly encountered in the Part D marketplace.

(3) Definition of “In Connection With the Utilization of Part D Drugs”

Section 1860D–12(h)(1)(A)(i) of the Act prohibits PBMs and their affiliates from deriving any remuneration other than bona fide service fees for any services in connection with the utilization of covered Part D drugs, from any entity or individual. Determining whether a payment arrangement is “in connection with the utilization of covered Part D drugs” establishes whether the prohibition in section 1860D–12(h)(1)(A)(i) of the Act applies. If a payment to a PBM is unrelated to the utilization of Part D drugs (as defined at § 423.100), the payment is not covered by this prohibition. Clarity in this prong of the prohibition is therefore important to ensure an appropriate scope that neither allows entities to circumvent the statutory prohibition by labeling payments as unrelated to Part D drugs even when such a connection exists, nor applies to payments that truly have no connection to Part D drug utilization.

For this reason, we are proposing to define what it means for remuneration to be in connection with the utilization

of Part D drugs. We also propose to clarify the treatment of remuneration arrangements that involve both Part D drugs and non-Part D drugs, because the prohibition applies specifically to remuneration received in connection with the utilization of Part D drugs, and not to remuneration received in connection with drugs dispensed under other benefit programs, such as Medicaid or commercial insurance.

We propose that remuneration is “in connection with the utilization of Part D drugs” if the remuneration relates to the prescribing, dispensing, furnishing, coverage, reimbursement, or management of Part D drugs, including activities that directly or indirectly influence or determine such utilization. For services supporting multiple lines of business, only the portion of remuneration allocable to the utilization of Part D drugs under a Part D plan would be considered to be in connection with such utilization.

This definition reflects two important principles. First, “in connection with utilization” is construed broadly to encompass the full range of activities that contribute to a Part D drug being prescribed, dispensed, furnished, covered, reimbursed, or managed on behalf of Part D enrollees. This includes not only the direct act of dispensing a drug but also upstream (for example, formulary placement, contracting with network pharmacies) and downstream (for example, processing and payment of prescription drug claims, adjudication of appeals or grievances related to the prescription drug benefit) activities that directly or indirectly influence or determine whether and how Part D drugs are utilized.

Second, we recognize that PBMs frequently administer benefits that span multiple lines of business, including Part D, Medicaid, and commercial insurance, and that a single service (and the remuneration associated with it) may not always be solely attributable to a single line of business. We propose a definition of “in connection with the utilization of Part D drugs” that is designed to reflect this reality by clarifying that “only the portion of remuneration allocable to the utilization of Part D drugs under a Part D plan is considered.” Therefore, we propose that, where a service performed by a PBM or its affiliate encompasses Part D drug utilization—even if it also encompasses non-Part D activity—only the portion of remuneration allocable to the utilization of Part D drugs under a Part D plan is subject to the bona fide service fee requirement.

This allocability standard would operate as follows. Where a PBM

performs a service that covers both Part D and non-Part D drug utilization, the total remuneration received for that service is not excluded from the prohibition simply because the service also encompasses activity that does not involve a Part D drug. Rather, the PBM must allocate the total remuneration between the portion that is in connection with the utilization of Part D drugs and portion that is not connection with the utilization of Part D drugs when reporting on remuneration to a Part D plan sponsor, following the standards at proposed § 423.2810(e)(1)(ii)(B). That portion allocated to the utilization of Part D drugs is the amount subject to the bona fide service fee requirement.

We propose to codify this definition at 423.2810(h). We seek comment on the proposal and whether the allocability standard described previously provides sufficient clarity and flexibility for PBMs and Part D plan sponsors to identify and allocate remuneration under mixed arrangements. We also seek comment on whether additional guidance or specific examples would be useful to address particular types of services or remuneration structures commonly encountered in the Part D marketplace.

(4) Fair Market Value for Bona Fide Service Fees

In accordance with section 1860D–12(h)(7)(B) of the Act, bona fide service fees must be “reflective of the fair market value (as specified by the Secretary, through notice and comment rulemaking)”. In specifying the meaning of fair market value for bona fide service fees, we considered definitions previously contemplated in federal rulemaking, including the *Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007* (“CY 2007 PFS”) and the *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* (“CY 2026 PFS”).

The CY 2007 PFS final rule established that, beginning with average sales price (ASP) reporting for sales during the first quarter of CY 2007, bona

fide service fees that are paid by a manufacturer to an entity, whether or not the entity takes title to the drug, are not considered price concessions under § 414.804(a)(2) insofar as, and to the extent that, they satisfy the definition of a bona fide service fee described at § 414.802: “fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.” The CY 2007 PFS final rule did not provide guidance on specific methodologies that manufacturers must use to determine fair market value.

The CY 2026 PFS proposed rule elaborated on the approach to fair market value, as applied to the definition of bona fide service fees that are not considered price concessions under § 414.804(a)(2). CMS proposed additional requirements for the standards and methodology that should be used to determine fair market value, specifically: for fees paid by a manufacturer to an entity that do not vary directly with the amount of drug sold or price of a manufacturer’s drug, the fair market value must be determined either based on comparable market transactions that generally reflect current market conditions or the cost of the service plus a reasonable markup to the total cost, and for fees paid by a manufacturer to an entity that vary directly with the amount of drug sold or price of a manufacturer’s drug, the fair market value must be determined by using the cost of the service and adding a reasonable markup to the total cost. CMS further proposed that for fees paid by a manufacturer to an entity that vary directly with the amount of drug sold or price of a manufacturer’s drug, if any material portion of cost data is not available, manufacturers should follow a market-based approach based on verifiable market data until such time as sufficient cost data becomes available. CMS additionally proposed that under such circumstances, the fair market value assessment must be conducted by an independent, third-party valuator that does not have any financial relationship (other than the arrangement to conduct fair market value analyses) with either party to the arrangement and no stake in the outcome of the valuation, and the assessment must be documented with a clear explanation, including a

description of the methodology used. Finally, CMS proposed to require that manufacturers update fair market analyses no less frequently than the renewal period of the agreement for the service arrangement between the manufacturer and the other entity and that they include documentation of the update in the reasonable assumptions documentation corresponding with the quarter when the update was made. CMS did not finalize these proposals, which were regulatory actions and not statutorily required, in the CY 2026 PFS final rule.

We believe that, of the previously approaches to fair market value previously contemplated by CMS, the approach proposed in the CY 2026 PFS proposed rule for purposes of average sales price reporting provides the most appropriate foundation for specifying the meaning of fair market value under Section 1860–D(h)(7)(B) of the Act, since it includes the most detail and was informed by market dynamics that CMS had observed since the earlier CY 2007 PFS rule. We are proposing a definition of fair market value that largely aligns with the approach in the CY 2026 PFS proposed rule, with some changes due to the differences between the programs and the introduction of additional requirements by the CAA. For example, because section 1860–D(h)(7)(B) of the Act specifies that bona fide service fees “shall not be directly or indirectly based on, or contingent upon” drug price, we are not proposing a separate fair market value standard for fees that vary with the manufacturer’s price of a drug. Additionally, our proposed definition would apply to a broader set of fees than those paid by a pharmaceutical manufacturer, since it would apply to any remuneration received by a PBM or any affiliates of such PBM from any individual or entity in connection with the utilization of Part D drugs. Finally, whereas the purpose of the CY 2026 proposed rule was to define bona fide service fees to inform average sales price reporting, the purpose of this rule is to define bona fide service fees in the broader context of the statutory requirement that generally prohibits PBMs and their affiliates from receiving remuneration other than bona fide service fees with respect to services provided on behalf of any entity or individual in connection with the utilization of Part D drugs.

We are proposing at § 423.2810(e)(1) that fair market value be defined as the cost of the itemized service plus a reasonable markup to the total cost, for all bona fide service fees. This single definition of fair market value for bona fide service fees differs from the

definition in the CY 2026 PFS proposed rule—which contemplated different standards for fees that do and do not vary directly with the amount of drug sold or price of a manufacturer's drug—because section 1860D–12(7)(B) provides that bona fide service fees may not be directly or indirectly based on or contingent upon drug price. Commenters did raise concerns with the cost-based definition of fair market value in response to the CY 2026 PFS proposed rule. Specifically, commenters argued that CMS should allow multiple valuation approaches (cost-, market-, income-based, or hybrid) to reflect market realities, that the existing average sales price framework for fair market value (which does not specify a particular valuation methodology) is adequate, and that fees based on a percentage of drug cost are not inherently improper. However, we believe those comments and concerns are not relevant to this proposal for several reasons. First, the context in which we are undertaking this rulemaking is different than the context in which the CY 2026 PFS was developed due to the unique requirements of section 1860D–12(h) of the Act, as added by the CAA. The CAA enumerated requirements for bona fide service fees and expressly instructed the Secretary to specify the meaning of fair market value, delegating authority to the Secretary to consider definitions of fair market value beyond the PFS framework, as well as imparting a statutory imperative to address fair market value (whereas the proposed definition of fair market value in the CY 2026 PFS rule was a regulatory action). Second, the CAA explicitly prohibits bona fide service fees from being tied to the price of a drug, so comments in response to the CY 2026 PFS proposed rule defending fees that are a percentage of drug cost are not relevant in the context of the CAA. Third, the comments in response to the CY 2026 PFS proposed rule contemplated the definition of fair market value specifically in the context of bona fide service fees that may be retained in the determination of average sales price reported to CMS by the manufacturer, rather than in the context of bona fide service fees received by any PBM or affiliate of such PBM in connection with the utilization of Part D drugs. We do not assume that the public comments submitted in response to the CY 2026 PFS proposed rule provide a comprehensive picture of sentiment regarding a cost-based definition of fair market value outside of the context of average sales price reporting, and we are

soliciting public comment on our proposed definition of fair market value for application in the context of regulations implementing section 1860D–12(h) of the Act.

If observed data on any material portion of the cost of the service are not available—for example, if the PBM or affiliate of such PBM begins providing a new service for the first time—we propose at § 423.2810(e)(1)(i) that the fair market value for the bona fide service fee be defined as an estimate of the expected cost of the itemized service plus a reasonable markup to the total cost, until such time as sufficient observed cost data are available. Sufficient observed cost data would be considered available no later than 1 year after the bona fide service fee based on estimated costs is in effect. In addition, we propose that the estimated cost be consistent with, if available, the cost to the PBM or affiliate of such PBM of providing other itemized services, with reasonable adjustments as necessary to account for bona fide differences between the resources needed to perform each itemized service. For example, a PBM or affiliate would use the actual labor costs associated with employees with similar credentials and job requirements who perform other itemized services on behalf of the PBM or affiliate when estimating the labor costs of providing a new itemized service for which any material portion of cost data is not available to the PBM or affiliate. We propose using an estimate of expected costs—rather than a market-based approach based on verifiable market data until such time as sufficient cost data becomes available as proposed in the CY 2026 PFS proposed rule—for several reasons. CMS received many comments in response to the CY 2026 proposed rule arguing that the proposed requirement for use of an independent, third-party valuator that does not have any financial relationship (other than the arrangement to conduct fair market value analyses) with either party to the arrangement and no stake in the outcome of the valuation would disrupt the market and add significant burden since there are few valuers that currently meet that requirement. We also believe that PBMs and their affiliates typically have either sufficient data on their own internal costs or a sufficient ability to estimate their own expected costs, such that a cost-based approach to fair market value is appropriate for any services provided by PBMs or their affiliates in connection with the utilization of Part D drugs.

To clarify what expenses should be considered costs, we examined existing federal regulations that address cost-

based compensation structures. Federal Acquisition Regulation (FAR) 31.201–1 describes the composition of total costs for federal acquisition as: “The total cost, including standard costs properly adjusted for applicable variances, of a contract is the sum of the direct and indirect costs allocable to the contract, incurred or to be incurred, plus any allocable cost of money pursuant to 31.205–10, less any allocable credits. In ascertaining what constitutes a cost, any generally accepted method of determining or estimating costs that is equitable and is consistently applied may be used.” FAR 31.201–2 describes requirements for the allowability of costs, including compliance with requirements of reasonableness, allocability, standards promulgated by the Cost Accounting Standards Board (an independent, statutorily established board that creates and maintains cost accounting standards for federal contracts), and the terms of the contract under which the costs are incurred. The FAR further defines reasonableness and allocability at FAR 31.201–3 and FAR 31.201–4 and discusses the treatment of credits in FAR 31.201–5.

The Office of Management and Budget (OMB) guidance on federal awards is similar to the regulations in the FAR in its instructions on identifying costs. OMB's guidance at 2 CFR 200.402 defines composition of costs as: “The total cost of a Federal award is the sum of the allowable direct and allocable indirect costs minus any applicable credits”. OMB's guidance at 2 CFR 200.403 describes factors affecting the allowability of costs. For example, allowable costs must be determined in accordance with generally accepted accounting principles (GAAP) with limited exceptions, must be adequately documented, and must be accorded consistent treatment (for example, a cost must not be treated as a direct cost if any other cost incurred for the same purpose in like circumstances has been allocated as an indirect cost). OMB's guidance at 2 CFR 200.404 and 200.405 further defines reasonable costs and allocable costs, and OMB's guidance at 2 CFR 200.406 discusses treatment of applicable credits.

While bona fide service fees under section 1860D–12(h) of the Act are for itemized services provided by PBMs and their affiliates to any individual or entity—which is unlikely to include services furnished to the government through a federal award—we propose to adopt some of the principles described in the previously regulations in order to establish consistency, fairness, and transparency in the determination of costs. Accordingly, we propose at

§ 423.2810(e)(1)(ii) to define the cost of an itemized service as “the sum of the allowable costs minus any applicable credits”. Furthermore, we propose that allowable costs must be reasonable, allocable, determined in accordance with generally accepted accounting principles (GAAP), supported by adequate documentation, and accorded consistent treatment.

We propose at § 423.2810(e)(1)(ii)(A) that a reasonable cost cannot exceed an amount that a prudent person would incur under the circumstances prevailing when the decision was made to incur the cost, in alignment with OMB’s guidance at 2 CFR 200.404, and further propose that in determining reasonableness, consideration must be given to the following: (1) whether the cost is generally recognized as ordinary and necessary for the recipient’s performance of the itemized service; (2) the restraints or requirements imposed by such factors as sound business practices; arm’s-length bargaining; Federal, State, local, tribal, and other laws and regulations; (3) the cost of comparable market transactions; (4) whether the cost represents a deviation from the recipient’s established written policies and procedures for incurring costs; (5) whether the cost is subject to any bias due to overlap between the individuals who negotiate the bona fide service fee and the individuals who negotiate remuneration or transactions other than bona fide service fees or incentive payments with the entity that pays the bona fide service fee; and (6) whether the cost is comparable to costs incurred for similar services in the general, non-health care market.

These requirements largely mirror the requirements for reasonableness at OMB’s guidance at 2 CFR 200.404. The requirement at § 423.2810(e)(1)(ii)(A)(5) addresses a concern that the negotiation of bona fide service fees between PBMs or affiliates of such PBMs and other entities could bias or be biased by the negotiation of other remuneration or transactions—such as rebates negotiated with manufacturers or payment rates negotiated with pharmacies—if the same parties are responsible for negotiating both bona fide service fees and the other remuneration or transactions. The requirement at § 423.2810(e)(1)(ii)(A)(6) attempts to prevent costs from continuing to be artificially inflated simply because the health care market has historically borne high costs.

We propose at § 423.2810(e)(1)(ii)(B) that in order for a cost to be generally allocable to an itemized service, the cost must be assignable to that itemized service in accordance with the relative

benefits received. This standard can be met if the cost satisfies any of the following criteria: (a) is incurred specifically for that itemized service; (b) benefits both the itemized service and other work of the recipient and can be distributed in proportions that may be approximated using reasonable methods; or (c) is necessary to the overall operation of the recipient and is assignable in part to the itemized service in accordance with these cost principles. We are also proposing the following:

- Section 423.2810(e)(1)(ii)(B)(2)(i): All itemized services which benefit from the recipient’s indirect cost will receive an appropriate allocation of indirect costs.

- Section 423.2810(e)(1)(ii)(B)(2)(ii): A cost allocable to a particular itemized service may not be allocated to other itemized services.

- Section 423.2810(e)(1)(ii)(B)(2)(iii): If a cost benefits two or more itemized services in proportions that can be determined without undue effort or cost, the cost must be allocated to the itemized services based on the proportional benefit.

However, when those proportions cannot be determined because of the interrelationship of the work involved, then, notwithstanding paragraph (e)(1)(ii)(B)(2)(ii), the costs may be allocated or transferred to itemized service on any reasonable documented basis.

Finally, with respect to allocability, we propose at § 423.2810(e)(1)(ii)(B)(3) that the data and assumptions used to allocate costs must be updated not less than annually. This requirement would ensure that bona fide services fees are tied to actual costs regardless of the level of service at which the bona fide service fee is determined. In a simplified example, assume that the primary cost underlying the service of claims adjudication for a given PBM is the development and maintenance of software, such that the cost to the PBM to process 1,000,000 claims in a year is the same as the cost to process 10,000,000 claims in a year. If the PBM defines the itemized service at the per-claim level and allocates the annual cost of providing the service using a projected number of claims processed, the aggregate bona fide service fees received by the PBM for the claims adjudication service in a plan year could fail to reflect cost if the actual number of claims processed under the agreement is significantly more or less than the projected number of claims. Annual updates to the data and assumptions used in the allocation of costs will ensure that bona fide service

fees remain reflective of underlying cost. To the extent that the PBM or affiliate of such PBM experiences economies of scale that cause the marginal cost per service to decrease as the amount of the service provided increases, the allocation of costs should reflect such information.

We propose at § 423.2810(e)(1)(ii)(B)(2)(iv) that applicable credits refer to transactions that offset or reduce direct or indirect costs allocable to an itemized service. Examples of such transactions are purchase discounts, rebates or allowances, recoveries or indemnities on losses, insurance refunds or rebates, and adjustments of overpayments or erroneous charges. To the extent that such credits accruing to or received by the recipient relate to allowable costs, they must be credited to the itemized service either as a cost reduction or cash refund, as appropriate.

We solicit comment on these proposals for defining allowable costs, including whether they provide sufficient safeguards to ensure that costs are not inappropriately inflated and unrepresentative of fair market value.

In addition to the previously proposals to apply certain requirements to allowable costs, we believe it is also appropriate to apply certain requirements to the definition of “reasonable” as it applies to reasonable markup of total costs in the determination of fair market value for bona fide service fees. As noted previously, both the FAR and OMB guidance apply a reasonableness requirement to costs for cost-based awards. We believe that it is appropriate to generally align the standard of reasonable markup with the reasonableness standards used in these regulations for consistency. However, because several elements of the definition of reasonable costs are specific to the core cost and would translate imperfectly to the concept of markup, we believe certain modifications are necessary. Therefore, we propose at § 423.2810(e)(1)(iii) that reasonable markup cannot exceed an amount that a prudent person would apply under the circumstances prevailing when the decision regarding the amount of the markup was made and further propose that in determining reasonableness, consideration must be given to the following: (1) the restraints or requirements imposed by such factors as sound business practices; arm’s-length bargaining; Federal, State, local, tribal, and other laws and regulations; (2) comparable market transactions; (3) whether the markup represents a deviation from the recipient’s

established written policies and procedures for determining markup; (4) whether the markup is subject to any bias due to overlap between the individuals who negotiate the bona fide service fee and the individuals who negotiate remuneration or transactions other than bona fide service fees or incentive payments with the entity that pays the bona fide service fee; and (5) whether the markup is comparable to markup applied for similar services in the general, non-health care market. We considered a single quantitative percent ceiling on reasonable markup but did not propose this option due to the diversity of entities that may fit the definition of PBM or affiliate of such PBM and the wide variation in the types of services they provide. We also considered not defining “reasonable” with respect to markup and instead requiring that the PBM or affiliate of such PBM disclose the percent of the markup to the entity paying the bona fide service fee. We solicit comment on our proposed requirements for reasonable markup, including whether there are additional requirements we should include.

We solicit comment on the previous proposals, including whether there are circumstances for which we should allow an alternative definition of fair market value for bona fide service fees, including but not limited to circumstances in which fair market value could be determined based on comparable market transactions. We also solicit comment on whether there are any requirements that should be placed on alternative mechanisms for defining fair market value, such as requiring use of an independent, third-party valuator without any financial relationship (other than the arrangement to conduct fair market value analyses) with either party to the arrangement and no stake in the outcome of the valuation.

Section 1860D–12(h)(7)(B) of the Act provides that bona fide service fees shall not be directly or indirectly based on, or contingent upon—(i) drug price, such as wholesale acquisition cost or drug benchmark price (such as average wholesale price); (ii) the amount of discounts, rebates, fees, or other direct or indirect remuneration with respect to Part D drugs dispensed to enrollees in a prescription drug plan, except as permitted pursuant to paragraph (1)(A)(ii); (iii) coverage or formulary placement decisions or the volume or value of any referrals or business generated between the parties to the arrangement; or (iv) any other amounts or methodologies prohibited by the Secretary. We are proposing to prohibit

two specific additional types of methodologies for calculating bona fide service fees at § 423.2810(b)(3).

First, we are proposing at § 423.2810(b)(3)(i) to prohibit a methodology that requires the entity paying the bona fide service fee to the PBM or affiliate of such PBM for an itemized service to pay any additional fee, including any additional fee that otherwise would meet the requirements of a bona fide service fee, in order to access the primary benefit of such itemized service or have access to sufficient information to provide oversight of such itemized service. For example, if a Part D plan sponsor contracts with a PBM to negotiate rebates with a pharmaceutical manufacturer and pays a bona fide service fee for that itemized service, the PBM or its affiliate may not require that the Part D plan sponsor pay a separate data access fee in order to obtain basic information about the negotiated rebate (because such information is necessary to provide oversight of the itemized service of rebate negotiation). We solicit comment on the proposal to prohibit this methodology, including whether any modifications are warranted to account for differences in services offered by different types of PBM affiliates.

Second, we are proposing at § 423.2810(b)(3)(ii) that a PBM or its affiliate may not make the availability of an itemized service contingent on an agreement that the entity or individual with which the PBM or its affiliate is contracting for such itemized service provide remuneration to the PBM or affiliate of such PBM for a separate service. We are proposing to define a separate service as an itemized service that is not necessary for the PBM or affiliate of such PBM to perform in order for the PBM or affiliate of such PBM to provide the itemized service under contract. Reasons a separate service may not be necessary include that the contracting entity does not require that service or that the contracting entity is able to fulfill the service without use of the PBM or its affiliate, either independently or through a different contract. For example, if a Part D plan sponsor establishes a remuneration agreement with a PBM to adjudicate claims on the Part D plan sponsor’s behalf, the PBM may not require that the agreement include the additional service of formulary development, because it is possible for the Part D plan sponsor to develop the formulary itself or contract with another entity to develop the formulary. This proposal would not prohibit the Part D plan sponsor in this scenario from

voluntarily choosing to contract with the PBM for the additional service of formulary development. We solicit comment on the proposal to prohibit this methodology, including on whether any modifications are warranted to account for differences in services offered by different types of PBM affiliates.

These proposed prohibitions anticipate and attempt to prevent a potential adverse effect of requiring a remuneration structure that is entirely fee-based: the proliferation of individual fees which may not deliver benefit to the paying individual or entity. There is some evidence of the market moving in this direction already, such as the consolidation of rebate negotiation with PBM GPOs that retain revenue by charging multiple flat fees.⁴¹

We solicit comment on additional or alternative methodologies that CMS should consider prohibiting.

b. Incentive Payments

In addition to bona fide service fees, the CAA also provides for certain limited incentive payments to PBMs. Section 1860D–12(h)(1)(A)(2) of the Act, as added by the CAA, states that an incentive payment (as determined by the Secretary) paid by a Part D plan sponsor to a PBM or an affiliate of a PBM that is performing services on behalf of such sponsor shall be deemed a ‘bona fide service fee’ (even if such payment does not otherwise meet the definition of such term under paragraph (7)(B)) if such payment is a flat dollar amount, is consistent with fair market value (as specified by the Secretary), is related to services actually performed by the PBM or affiliate of such PBM, on behalf of the Part D plan sponsor making such payment, in connection with the utilization of Part D drugs, and meets additional requirements, if any, as determined appropriate by the Secretary. We propose to codify these requirements at § 423.2810(c). An incentive payment would be a reasonable form of remuneration in targeted circumstances under which the Part D plan sponsor is incentivizing or rewarding measurable performance by a PBM or an affiliate of such PBM. It should not be treated as an alternative payment structure to bona fide service fees that serves to enhance overall compensation rather than rewarding higher levels of performance.

We believe that fair market value should be defined differently for incentive payments than for bona fide service fees. While a cost-based

⁴¹ <https://www.ftc.gov/reports/pharmacy-benefit-managers-report>.

definition is appropriate for determining the fair market value for bona fide service fees (proposed at § 423.2810(e)(1)), it may not necessarily be appropriate for incentive payments given that the cost to provide an itemized service may not differ meaningfully based on the quality of performance. Therefore, we believe it is appropriate to define fair market value for incentive payments on the basis of something other than cost. The definition of fair market value proposed in the CY 2026 PFS proposed rule included the concept of comparable market transactions, which we believe to be an appropriate basis for incentive payments since such an approach would allow Part D plan sponsors to offer meaningful incentives based on performance (rather than cost) while preventing remuneration structures that are untethered from actual market conditions. We propose at § 423.2810(e)(2) that fair market value for incentive payments be defined as an amount reflective of comparable market transactions that generally reflect current market conditions.

We solicit comment on this proposal, including whether it allows Part D plan sponsors to provide meaningful performance incentives to PBMs and affiliates of PBMs without creating an alternative remuneration structure that serves to enhance overall compensation rather than rewarding higher levels of performance. We specifically solicit comment on whether the proposals provide sufficient clarity regarding the circumstances under which incentive payments are a reasonable alternative to bona fide service fees.

c. Exception for Manufacturer Rebates, Discounts, and Price Concessions.

Section 1860D–12(h)(1)(A)(i) of the Act establishes a general rule prohibiting a PBM and its affiliates from deriving “any remuneration with respect to any services provided on behalf of any entity or individual, in connection with the utilization of covered Part D drugs” other than bona fide service fees. Section 1860D–12(h)(1)(A)(iii) of the Act creates an exception to that general rule for certain manufacturer rebates, discounts, and other price concessions.

That exception provides: “Rebates, discounts, and other price concessions received by a PBM or an affiliate of a PBM from manufacturers, even if such price concessions are calculated as a percentage of a drug’s price, shall not be considered a violation of the requirements of clause (i) if they are fully passed through to a PDP sponsor and are compliant with all regulatory

and subregulatory requirements related to direct and indirect remuneration for manufacturer rebates, discounts, and other price concessions under this part, including in cases where a PDP sponsor is acting as a pharmacy benefit manager on behalf of a prescription drug plan offered by such PDP sponsor.”

For a rebate, discount, or other price concession to qualify for this exception, two conditions must be satisfied: (1) the price concession must be fully passed through to the Part D plan sponsor; and (2) the price concession must comply with all regulatory and subregulatory requirements related to DIR under Part D.

The statute also expressly permits price concessions calculated as a percentage of a drug’s price, extends the exception to both PBMs and their affiliates, and explicitly covers scenarios in which a Part D plan sponsor acts as its own PBM.

To establish the parameters of this exception, CMS proposes to specify: (1) when a price concession has been fully passed through to the Part D plan sponsor; (2) what process must be followed for price concessions received by affiliates; and (3) how compliance with DIR requirements will be determined.

As a threshold matter, the standard Part D benefit and Part D payment framework require plan costs to be determined based on costs actually incurred.⁴² CMS has long implemented that requirement through regulations providing that Part D costs be reported net of applicable DIR. Notably, consistent with that statutory foundation, 42 CFR 423.308 defines amounts “actually paid” to mean costs that are actually incurred by the Part D plan sponsor and are net of any DIR. DIR is further defined to include all “price concessions or similar benefits from manufacturers, pharmacies, or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the DIR or passes the entire DIR to the Part D plan sponsor.” 42 CFR 423.100 in turn defines “price concession” to mean “any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor.”

⁴² See, for example, section 1860D–2(d)(1) of the Act.

Although section 1860D–12(h)(1)(A)(iii) of the Act refers to “rebates, discounts, and other price concessions,” we believe it is reasonable to interpret those terms by reference to the existing Part D definitions of “price concession” at 42 CFR 423.100 and DIR within “actually paid” at 42 CFR 423.308.

Therefore, we propose, at 42 CFR 423.2810(d)(1), to interpret “rebates, discounts, and other price concessions” for purposes of section 1860D–12(h)(1)(A)(iii) of the Act by reference to those existing definitions. Under that interpretation, the exception applies only to the subset of price concessions and DIR that are: (1) received by a PBM or PBM affiliate from a manufacturer; (2) attributable to covered Part D drug utilization; (3) fully passed through to the Part D plan sponsor; and (4) compliant with applicable regulatory and subregulatory DIR requirements under Part D. Remuneration from non-manufacturer entities would not qualify for this exception as proposed.

In determining when a payment is “fully passed through,” an important principle can be derived from the existing Part D framework. Under 42 CFR 423.308, costs must be net of any DIR from any source that would decrease costs incurred under the Part D plan. That framework focuses on the economic value of the concession and requires that any remuneration decreasing plan costs be reflected in Part D cost calculations.

We believe a consistent approach should govern the definition of “fully passed through” in order to ensure alignment with the existing DIR framework. Therefore, we propose, at 42 CFR 423.2802, to define “fully passed through” to mean that the Part D plan sponsor receives 100 percent of the gross economic value of each manufacturer rebate, discount, or other price concession attributable to covered Part D drug utilization. We also propose to specify that the standard for “fully passed through” would not be met if a PBM or PBM affiliate reduces, offsets, nets, holds back, retains, reclassifies, or otherwise diminishes the value passed through to the Part D plan sponsor, including through administrative fees, data fees, aggregation fees, reconciliation charges, or other deductions.

We propose at § 423.2810(d)(2)(iii) that a manufacturer rebate, discount, or other price concession cannot satisfy the DIR compliance condition unless the price concession is: accurately classified; allocated to the appropriate plan, drug, NDC, utilization period, and plan year; reported in the Summary and

Detailed DIR Data Reports or successor reporting mechanism as required by CMS; reflected in applicable Part D reconciliation and payment processes; and supported by records sufficient for audit. A price concession that is retained by a PBM or PBM affiliate, misclassified as a service fee, omitted from DIR reporting, or otherwise not reflected in Part D reconciliation would not qualify for the exception; however, a noncompliant price concession may be corrected in accordance with CMS's applicable correction, reopening, reconciliation, or audit processes, including completion of any required pass-through, disgorgement, and corrected reporting.

Finally, we propose at 42 CFR 423.2810(d)(3) that manufacturer rebates, discounts, and other price concessions received by an affiliate of a PBM would be treated the same as concessions received directly by the PBM.

We request comment on this proposal.

d. Rule of Construction

As discussed earlier in section 6 of this proposed rule, section 1860D–12(h)(1)(A)(i) of the Act establishes the general remuneration restriction for PBMs and PBM affiliates. Under that provision, a PBM or PBM affiliate may not derive remuneration in connection with services provided on behalf of an entity or individual and related to the utilization of Part D drugs, unless the remuneration is a bona fide service fee, subject to section 1860D–12(h)(1)(A)(ii) or (iii) of the Act.

Section 1860D–12(h)(4) of the Act includes a rule of construction addressing certain pharmacy and wholesaler payment arrangements. Specifically, section 1860D–12(h)(4)(A) of the Act provides that nothing in subsection (h) of the Act shall be construed as prohibiting flat dispensing fees or reimbursement or payment for ingredient costs, including customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers, to entities that acquire or dispense prescription drugs. Section 1860D–12(h)(4)(B) of the Act further provides that nothing in subsection (h) of the Act shall be construed as modifying regulatory requirements or subregulatory program instruction or guidance related to pharmacy payment, reimbursement, or dispensing fees.

We propose to codify the statute's rule of construction at proposed § 423.2810(i). Specifically, we propose to codify at proposed § 423.2810(i)(1) that the requirements for remuneration to PBMs and their affiliates to be

codified at proposed § 423.2810 would not prohibit flat dispensing fees, or reimbursement or payment for ingredient costs, including customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers, to entities that acquire or dispense prescription drugs. Additionally, we propose to codify at proposed § 423.2810(i)(2) that the requirements for PBM remuneration codified at proposed § 423.2810 do not modify regulatory requirements or subregulatory program instructions or guidance related to pharmacy payment, reimbursement, or dispensing fees.

As discussed previously, PBMs may operate as part of vertically integrated entities or other ownership and control relationships with retail pharmacies, mail order pharmacies, specialty pharmacies, long-term care pharmacies, or wholesalers as described in proposed § 423.2806(a). PBMs may also have functional relationships under which a pharmacy or wholesaler may be an affiliate of the PBM as described in proposed § 423.2806(b). While the rule of construction excludes specific pharmacy and wholesaler payments from the requirements of subsection (h) of the Act, the rule of construction does not create a blanket exemption whereby all payments to pharmacies or wholesalers that are affiliated with a PBM are automatically exempted from the PBM and affiliate remuneration requirements of section 1860D–12(h) of the Act. Rather, the rule of construction is a constraint on the application of the requirements of section 1860D–12(h) of the Act in the specific circumstances identified by statute.

Accordingly, the rule of construction being codified at proposed § 423.2810(i)(1) would limit the application of the remuneration restrictions at section 1860D–12(h)(1)(A) of the Act to a wholesaler or pharmacy that is an affiliate of a PBM in those particular circumstances in which the application of the remuneration restrictions would prohibit dispensing fees, reimbursement, or payments directly protected by statute. Likewise, the rule of construction being codified at proposed § 423.2810(i)(2) would limit the application of the remuneration restrictions at section 1860D–12(h)(1)(A) of the Act in those particular circumstances in which the application of the remuneration restrictions would not be consistent with an applicable regulation, program instruction or guidance that establishes requirements for pharmacy payment, reimbursement or dispensing fees without modification to such regulation, program instruction

or guidance. We believe this approach will appropriately restrict remuneration to PBMs and their affiliates, while continuing to allow pharmacies, including pharmacies affiliated with a PBM, to receive and retain without modification those particular payments, reimbursement and dispensing fees where such remuneration is expressly permitted under applicable regulation, program instruction or guidance. We offer two examples of specific circumstances where the rule of construction is implicated.

First, a pharmacy, including a pharmacy affiliated with a PBM, may receive and retain reimbursement from a Part D plan sponsor for dispensing a covered Part D drug when the reimbursement reflects a negotiated price equal to a pricing standard such as average wholesale price, plus a flat dispensing fee. Reimbursement for dispensing a covered Part D drug is a payment that would fall within the rule of construction in section 1860D–12(h)(4)(A) of the Act to be codified at proposed § 423.2810(i)(1) and would not be constrained under the proposed restrictions on remuneration described in proposed § 423.2810(a) through (d) even if the remuneration is paid to a pharmacy that is affiliated with a PBM.

Second, the CMS program instructions to implement the Medicare Drug Price Negotiation Program establish specific parameters under which a Primary Manufacturer may make a retrospective MFP refund to a pharmacy or other dispensing entity to provide access to the MFP for a selected drug.⁴³ The MFP refunds to pharmacies and other dispensing entities described in this program instruction constitute payments for ingredient costs, including an acquisition-related discount, that would fall within the rule of construction in section 1860D–12(h)(4)(A) of the Act to be codified at proposed § 423.2810(i)(1) and would not be constrained under the proposed restrictions on remuneration described in proposed § 423.2810(a) through (d) even if the remuneration is paid to a pharmacy that is affiliated with a PBM. Moreover, these CMS program instructions establish that the Primary manufacturer's MFP refunds are to be paid to the dispensing entity to provide the dispensing entity with access to the MFP. In contrast, section 1860D–12(h)(1)(A)(iii) of the Act as described in

⁴³ See, for example, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 § 40.4 (September 30, 2025).

proposed § 423.2810(d) establishes that, for a price concession to a PBM or its affiliate to avoid the remuneration restrictions as described in proposed § 423.2810(b), such price concession must be fully passed through to the Part D plan sponsor. If CMS were to construe section 1860D–12(h)(1)(A) of the Act as described in proposed § 423.2810 as requiring an affiliate pharmacy to pass through its MFP refunds to the Part D plan sponsor in order for the MFP refund to be permissible remuneration, this application of the remuneration restrictions in section 1860D–12(h)(1)(A) of the Act would be inconsistent with the applicable Medicare Drug Price Negotiation Program program instructions, which establish that MFP refunds are to provide access to the MFP to the dispensing entity. Because the application of the remuneration restrictions in proposed § 423.2810(a)–(d) to MFP refunds would not be consistent with allowing affiliate pharmacies to receive and retain MFP refunds that are expressly permitted under the Medicare Drug Price Negotiation Program’s program instruction, the rule of construction in section 1860D–12(h)(4)(B) of the Act to be codified at proposed § 423.2810(i)(2) applies and such MFP refunds would not be constrained under the proposed restrictions on remuneration described in proposed § 423.2810(a) through (d) even if such remuneration is paid to a pharmacy that is affiliated with a PBM. We anticipate the same result in connection with future regulations codifying the Medicare Drug Price Negotiation Program’s program instruction.

We solicit comments on this proposal. In particular, we solicit comment on whether there are other types of payments, reimbursements, fees, or acquisition-related discounts received by pharmacies or wholesalers, or particular regulatory requirements, program instruction, or guidance related to pharmacy payment, reimbursement, or dispensing fees other than those discussed here for which additional clarification as to their status under section 1860D–12(h)(4) of the Act and this proposal would be useful. We also solicit comments on the implications that this rule of construction and the limitations on payment to affiliated pharmacies may have on the codification and enforcement of the standards for reasonable and relevant terms and conditions for pharmacy contracts described in section 1860D–4(B)(1)(A)(ii) of the Act. In particular, we are interested in the implications

this proposal would have on any requirements that might be promulgated with respect to pricing transparency and reimbursement in pharmacy contracts.

e. Disgorgement of Remuneration to the Part D Plan Sponsor

Section 1860D–12(h)(1)(A)(v) of the Act, as added by the CAA, provides that the written agreement between the Part D plan sponsor and PBM require that the PBM shall disgorge to the Part D plan sponsor any remuneration paid to such PBM or an affiliate of such PBM in violation of the requirements described at section 1860D–12(h)(1)(A) of the Act. We interpret this requirement to mean that if remuneration received by a PBM or affiliate of such PBM is in violation of the requirements described at section 1860D–12(h)(1)(A) of the Act, the total amount of such remuneration should be disgorged to the PDP sponsor. For example, if a PBM were to receive a manufacturer rebate in connection with a covered Part D drug and did not fully pass through the rebate to the Part D plan sponsor in accordance with section 1860D–12(h)(1)(A)(iii), the rebate, inclusive of both the portion already passed through to the Part D plan sponsor and the portion that was retained by the PBM, would be considered remuneration in violation of such requirements and must be disgorged by the PBM to the Part D plan sponsor, which in turn must disgorge the same amount to CMS as discussed at proposed § 423.2920(a). As another example, if an audit by a Part D plan sponsor were to identify that remuneration paid by an entity to a PBM was not in compliance with bona fide service fee requirements because it was not reflective of fair market value, all such remuneration must be disgorged to the Part D plan sponsor. We propose to codify this requirement at § 423.2810(g).

We considered an alternative interpretation through which only the amount of remuneration in excess of what the remuneration would have been had it been compliant with the requirements described at section 1860D–12(h)(1)(A) of the Act would be required to be disgorged to the Part D plan sponsor. Under this alternative, the PBM or affiliate of such PBM would have identified the counterfactual remuneration that would have been compliant with the requirements described at section 1860D–12(h)(1)(A) of the Act, and CMS could request documentation of the assumptions and methodology used to determine the amount of remuneration that was in violation and require modifications as determined necessary by CMS. For

example, under this alternative, if remuneration received by a PBM did not meet the bona fide service fee requirements because it was not reflective of fair market value, the PBM would determine what amount the remuneration would have been had it been reflective of fair market value and would disgorge the difference between that counterfactual amount and the actual amount of remuneration to the PDP sponsor. We did not propose this interpretation for several reasons. First, section 1860D–12(h)(1)(A)(v) of the Act applies the disgorgement requirement to “any remuneration paid to such pharmacy benefit manager or an affiliate of such pharmacy benefit manager in violation of this subparagraph”, not the difference between the violative amount and a counterfactually non-violative amount. Additionally, determining a methodology to calculate the counterfactually non-violative amount could be complex, for example if the remuneration violated the requirements at section 1860D–12(h)(1)(A) of the Act in multiple ways. Finally, remuneration is typically negotiated between parties to a contract, and it may be difficult to determine a counterfactual amount outside of that negotiation process.

We solicit comment on our interpretation of this requirement at section 1860D–12(h)(1)(A)(v) of the Act.

Section 1860D–12(h)(1)(A)(vi) of the Act requires that the PBM enter into an agreement with any affiliate of such PBM, under which the affiliate must identify and disgorge any remuneration paid to the affiliate in violation of the requirements described at section 1860D–12(h)(1)(A) of the Act to the PBM. We propose to codify this requirement at § 423.2810(g)(3). The same section also requires that the PBM attest, subject to any requirements determined appropriate by the Secretary, that the PBM has entered into such a written agreement with any affiliate of such PBM. We propose to require that the written agreement between the Part D plan sponsor and the PBM include this attestation at § 423.2810(g)(3)(i).

We also propose at § 423.2810(g)(1) and § 423.2810(g)(2) that for plan years beginning on or after January 1, 2028, the written agreement between a Part D plan sponsor and any PBM acting on behalf of such sponsor include the following requirements: (1) the PBM or any affiliate of such PBM must disgorge any remuneration paid to such PBM or affiliate if such PBM in violation of the requirements described at § 423.2810(a) no later than the earlier of: (i) 30 days following the conclusion of an audit by the Part D plan sponsor, as allowed at

§ 423.2814, that found remuneration paid to the PBM or affiliate of such PBM in violation of the requirements described at § 423.2810(a); or (ii) 30 days following the end of the month in which the PBM or affiliate of such PBM identified remuneration paid to the PBM or affiliate of such PBM in violation of the requirements described at § 423.2810(a); and (2) the PBM or affiliate of such PBM must provide the following information to the Part D plan sponsor: the amount of the remuneration in violation of the requirements described at § 423.2810(a), the entity from which such remuneration derived, the entity that received such remuneration, and the nature of the violation. With regards to the first requirement, we clarify that, under our proposal, if the PBM or affiliate of such PBM identifies remuneration paid to the PBM or an affiliate of such PBM in violation of the requirements at § 423.2810(a) during an audit by the Part D plan sponsor as allowed at § 423.2818 and prior to the conclusion of such audit, thirty days following the end of the month in which the PBM or affiliate of such PBM identified remuneration paid to the PBM or affiliate of such PBM in violation of the requirements described at § 423.2810(a) would be considered the earlier of the dates described previously.

We seek comment on our proposal at § 423.2810(f) for disgorgement of funds from the PBM to the Part D plan sponsor, specifically the requirements for timing of disgorgement.

f. Evaluation of Remuneration Agreements

Section 1860D–12(h)(1)(A)(iv) of the Act, as added by section 6224 of the CAA, provides that components of subsets of remuneration arrangements, such as fees or other forms of compensation paid to or retained by the PBM or affiliate of the PBM, between PBMs or PBM affiliates and other entities involved in the dispensing or utilization of covered Part D drugs shall be subject to review by the Secretary, in consultation with the Office of Inspector General of the Department of Health and Human Services (OIG), as determined appropriate by the Secretary. Section 1860D–12(h)(1)(A)(iv) of the Act further provides that the Secretary, in consultation with the Secretary, shall review whether remuneration under such arrangements is consistent with fair market value, as specified by the Secretary.

As discussed in section II.C.3. of this proposed rule, we propose at § 423.2810(e)(1) to define fair market

value for bona fide service fees based on the cost of the itemized service plus a reasonable markup to total cost. We also propose that, if observed cost data are not available, the fair market value for bona fide service fees may be based on expected cost plus a reasonable markup until sufficient observed cost data become available.

We propose to establish a two-part process for CMS to collect the information necessary to review whether remuneration arrangements involving PBMs and PBM affiliates are consistent with fair market value, as described at proposed § 423.2810(e), and otherwise comply with section 1860D–12(h) of the Act. This process would take place following the submission of the annual PBM reports, as proposed at § 423.2814.

In the first part of the process, CMS would identify a subset of PBMs for which components of a subset of their remuneration arrangements will be reviewed using a two-pronged sampling approach. First, CMS would review the annual PBM report, as proposed at § 423.2814, and any other available information to identify PBMs whose reported data warrant additional review. Second, to promote review of a broad range of PBM remuneration arrangements over time, CMS would also select a random sample of PBMs. For each PBM selected under either prong, CMS would select a sample of Part D plan sponsors with which the selected PBM has a written agreement to act on behalf of the Part D plan sponsor. All remuneration agreements held by the selected PBM, as well as those held by a sample of any affiliates of such PBM (selected by CMS from the list of affiliates reported by the PBM under the annual report described at § 423.2814), with any individual or entity, under which the PBM or affiliate of such PBM receives remuneration for services in connection with Part D drug benefits of the plan of that Part D plan sponsor would be subject to review. We propose at § 423.2810(f)(8) and § 423.2810(f)(9) this process for selecting PBMs and subsets of the remuneration arrangements of such PBMs and their affiliates for submission and review.

CMS would notify each selected PBM and, as described in proposed § 423.2810(f)(4), each selected PBM would be required to include in the summary of components of subsets of remuneration arrangements required to be submitted in the form and manner, and by the deadline, specified by CMS, all components of remuneration arrangements described in proposed § 423.2810(f)(9), that is, all remuneration arrangements between

itself or any of its selected affiliates and any other individual or entity under which the PBM or affiliate of such PBM receives remuneration for services in connection with the utilization of Part D drugs by enrollees in a prescription drug plan offered by such Part D plan sponsor. As described in proposed § 423.2810(f)(4)(ii), the summary of components of subsets of remuneration arrangements must identify each remuneration arrangement at the level needed to identify and classify each distinct remuneration structure and classify amounts received or retained by the selected PBM or its selected affiliates. Proposed § 423.2810(f)(4)(iii) would establish specific information that the PBM must include in its summary, for each remuneration arrangement and payment stream. We propose the PBM's summary must include the following information: the payer of the remuneration; the recipient of the remuneration; the affiliate status of the payer and recipient in relation to the PBM; the applicable Part D plan sponsor, contract, and plan; the service or payment category for the remuneration; a brief description of the remuneration arrangement or payment stream; the total amount of remuneration paid, received, and retained by the recipient; the amount of remuneration attributable to the utilization of covered Part D drugs; and the unit of payment or fee methodology used by the payer to determine the amount of remuneration. We propose the PBM's summary must also address: whether the arrangement or payment stream covers multiple services, entities, functions, or both Part D and non-Part D lines of business and whether the arrangement or payment stream is bundled, and, if applicable, must provide information regarding these aspects of the arrangement or payment. We propose the PBM's summary must classify remuneration under each arrangement or payment as a bona fide service fee, incentive payment, fully passed-through rebate, discount or other price concession, protected amount as described in the rule of construction at § 423.2810(i), or other remuneration. In addition, as described at proposed § 423.2810(f)(4)(iv), the PBM's summary would also be required to provide a crosswalk sufficient for CMS to identify the location in the remuneration agreement where each of those elements may be found.

In the second part of the process, as described at proposed § 423.2810(f)(5), CMS could request additional substantiation from the selected PBMs and their affiliates when CMS

determines that it is necessary to assess whether the remuneration is consistent with fair market value and otherwise complies with section 1860D–12(h) of the Act. For example, CMS could determine the need for additional substantiation based on the annual PBM report as proposed in § 423.2814, the Part D plan sponsor certification as proposed in § 423.2820(e), or the summary of components of subsets of remuneration arrangement as proposed in § 423.2810(f). CMS could also determine the need for additional substantiation based on allegations of misconduct received through the confidential reporting as proposed in § 423.2820(d) or otherwise. For arrangements for which CMS requests additional substantiation, the selected PBM would be required to submit information as specified by CMS sufficient to support the PBM's classification of the remuneration and CMS's evaluation of compliance with section 1860D–12(h) of the Act. Such information may include, but is not limited to, cost support showing the resources used to perform the service, such as direct labor, labor rates, personnel or time allocation, technology or vendor costs, overhead allocation, indirect administrative costs, and profit margin or markup; and fair market value support, including the valuation methodology, key assumptions, valuation date, preparer, comparable market data if used, cost-plus analysis if used, and any third-party valuation materials. The PBM may also be required to submit allocation support for arrangements involving multiple services, multiple entities, PBM and non-PBM functions, or both Part D and non-Part D lines of business. We propose at § 423.2810(f)(5) to provide that CMS may request additional substantiation for selected remuneration arrangements to be submitted in a form and manner specified by CMS.

We propose that PBMs, rather than Part D plan sponsors, submit the summary as described in proposed § 423.2810(f)(4) and any additional substantiation as described in proposed § 423.2810(f)(5) directly to CMS. Consistent with our contracting authority under sections 1860D–12(b)(3)(D) and (h)(1) of the Act, we propose the Part D plan sponsor would remain responsible for ensuring, through the written agreement with the PBM, that the PBM submits this information to CMS and provides information necessary for the Part D plan sponsor's annual certification as proposed in § 423.2820(e). We believe direct PBM submission of information

under this proposed § 423.2810(f) is appropriate because PBMs and their affiliates generally possess the relevant cost data, fair market value analyses, and contract support that would be required to file and substantiate the required reports. Direct submission to CMS also addresses concerns that some information may include trade secrets or other confidential business information that should not be disclosed more broadly than necessary. While information submitted under the process described in proposed § 423.2810(f) would be subject to the confidentiality protections in section 1860D–12(h)(6) of the Act, as applicable, we believe that allowing PBMs to submit such information to CMS directly rather than through the Part D plan sponsor will further protect proprietary information of the PBMs and their affiliates.

We propose at § 423.2810(f)(4) to require selected PBMs to each submit its summary of components of subsets of remuneration arrangements at a later date than the annual PBM report required under § 423.2814. We propose at § 423.2810(f)(6) to provide that information submitted under this proposed § 423.2810(f) would be subject to the confidentiality protections in section 1860D–12(h)(6) of the Act as described at proposed § 423.2822, as applicable.

We propose at § 423.2810(f)(7) that a PBM is responsible for obtaining from its affiliates and submitting to CMS information required under this section that is owned, held, or controlled by an affiliate of the PBM.

We solicit comments on this proposal, including the proposed sampling approach, the appropriate approach for random selection, the factors CMS should use to identify remuneration arrangements between PBMs and Part D plan sponsors for additional review, the number of PBMs CMS should annually select, the amount of time necessary for selected PBMs to prepare reporting after being notified of their selection, and whether alternative sampling methods would better balance program integrity with reporting burden.

7. Transparency Regarding Guarantees and Cost Performance Evaluations

Section 1860D–12(h)(1)(B) of the Act, as added by the CAA, requires that for plan years beginning on or after January 1, 2028, each contract entered into with a Part D plan sponsor under section 1860D–12 with respect to a prescription drug plan offered by such sponsor shall provide that any PBM acting on behalf of such sponsor has a written agreement with the Part D plan sponsor under

which the PBM agrees to define, interpret, and apply terms in a fully transparent and consistent manner, for purposes of calculating or otherwise evaluating PBM performance against pricing guarantees or similar cost performance measurements.

Pricing guarantees are a common feature of agreements between Part D plan sponsors and PBMs in which PBMs guarantee an effective rate, often expressed in terms of a percent off a reported price, paid by the Part D plan sponsor across a category of drugs, such as generic, brand, or specialty drugs.⁴⁴ For example, PBMs may guarantee to Part D plan sponsors an effective rate of 25 percent off average wholesale price for all brand drugs; the PBM would reconcile actual payments for ingredient cost of such drugs against the guaranteed price across the entire category of drugs by reimbursing the Part D plan sponsor for any excess payment or retaining the difference between the guarantee and the lower amount paid to the PBM. However, imprecise or non-standardized definitions of terms such as “brand”, “generic”, or “specialty” may allow PBMs to categorize drug products in ways that maximize their ability to retain revenue via effective rate guarantees.⁴⁵ For example, if a PBM were to guarantee 60 percent off average wholesale price for generic drugs but only 20 percent off average wholesale price for specialty drugs, assuming that the PBM paid pharmacies less than the guaranteed rate for a given drug, the PBM could retain more of the difference between the guaranteed rate and the amount paid to the pharmacy if it were to categorize the drug as a specialty drug rather than a generic drug.

PBM revenue retained via pricing guarantees as described previously would not meet the requirements of bona fide service fees introduced by section 1860D–12(h)(1)(A) of the Act, since such revenue would be contingent upon both the price of the drug and DIR. However, section 1860D–12(h)(1)(A)(ii) of the Act provides that an incentive payment paid by a Part D plan sponsor to a PBM or an affiliate of such PBM that is performing services on behalf of such sponsor may be deemed a ‘bona fide service fee’ if it meets certain

⁴⁴ https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

⁴⁵ <https://www.managedcaremag.com/archives/2010/9/when-brand-generic-contract-pbm/>; <https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize>; https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; <https://www.46brooklyn.com/research/2023/5/10/how-pbms-distort-and-undermine-specialty-drug-pricing-guarantees-blac>.

requirements. Therefore, Part D plan sponsors may offer incentive payments to PBMs for achieving pricing guarantees, provided those incentive payments meet all requirements described at proposed § 423.2810(c).

Section 1860D–12(h)(1)(B)(i) of the Act requires that PBMs define, interpret, and apply, in a fully transparent and consistent manner for purposes of calculating or otherwise evaluating PBM performance against pricing guarantees or similar cost performance measurements related to rebates, discounts, price concessions, or net costs, terms such as the following:

- ‘Generic drug’, in a manner consistent with the definition of the term under section 423.4 of title 42, Code of Federal Regulations, or a successor regulation.
- ‘Brand name drug’, in a manner consistent with the definition of the term under section 423.4 of title 42, Code of Federal Regulations, or a successor regulation.
- ‘Specialty drug’.
- ‘Rebate’.
- ‘Discount’.

We propose to adopt this requirement at § 423.2812(a)(1). We are also proposing at § 423.2812(b) that definitions of such terms be included in the written agreement between Part D plan sponsors and PBMs and that PBMs provide a list of drugs, including the NDC–11 or NDC–12 identifier of each drug, included in each category including “generic drug”, “brand name drug”, “specialty drug”, or any other categories of drugs for which PBM performance against pricing guarantees or similar cost performance metrics is measured to Part D plan sponsors, upon request of the Part D plan sponsor, not less than annually.

Section 1860D–12(h)(1)(B)(ii) of the Act requires that PBMs identify any drugs, claims, or price concessions excluded from any pricing guarantee or other cost performance measure in a clear and consistent manner. We propose at § 423.2812(c) to require that the PBM provide such a list of drugs, claims, or price concessions to Part D plan sponsors with sufficient information for the Part D plan sponsor to clearly identify such drugs, claims, or price concessions—including NDC–11 or NDC–12 identifiers for such drugs, identifying information about such claims such as date of service and beneficiary identifier, and information about such price concessions such as the amount of the price concession and the drug(s) to which it applies—upon request of the Part D plan sponsor, not less than annually.

Section 1860D–12(h)(1)(B)(iii) of the Act requires that where a pricing guarantee or other cost performance measure is based on a pricing benchmark other than the wholesale acquisition cost (as defined in section 1847A(c)(6)(B) of the Act) of a drug, the PBM calculate and provide a wholesale acquisition cost-based equivalent to the pricing guarantee or other cost performance measure. We propose to adopt this requirement at § 423.2812(a)(2). We are also proposing at § 423.2812(d) that PBMs disclose the source of the wholesale acquisition cost used in this equivalent pricing guarantee (for example, the name of the third-party pricing compendium from which the PBM derived the wholesale acquisition cost).

CMS considered whether the requirements discussed in this section of the proposed rule should apply to effective rate guarantees between PBMs and pharmacies. We are not including specific proposals regarding such guarantees in this rule but may address this topic in future rulemaking.

We solicit comment on these proposals related to transparency regarding guarantees and cost performance evaluations, including whether additional guardrails or definitions are necessary to achieve the objective of providing Part D plan sponsors with clear and transparent information about the performance of PBMs or their affiliates against cost performance metrics.

8. Annual PBM Reporting Requirements

Section 6224 of the CAA added section 1860D–12(h)(1)(C) of the Act, requiring that not later than July 1 of each year, beginning in 2028, the PBM shall submit a report, in a format specified by the Secretary, to the Part D plan sponsor and the Secretary with certain information with respect to the previous plan year. We propose to adopt this requirement at § 423.2814(a). Section 1860D–12(h)(1)(C) of the Act requires Part D plan sponsors to incorporate the requirement for PBMs to submit the described data into the written agreements between the Part D plan sponsor and the PBM. Consistent with our authority under sections 1860D–12(b)(3)(D) and (h)(1) of the Act, we propose the following requirements regarding the collection of these data and detailed definitions of such data for the purposes of carrying out section 1860D–12(h)(1)(C) of the Act.

CMS intends to use the CMS Health Plan Management System (HPMS) to collect this information. While there are no existing reporting requirements for PBMs to submit information to HPMS

prior to this statute, many PBMs have user accounts and submit information such as detailed DIR to CMS on behalf of Part D plan sponsors. Therefore, we believe that the system has both the functionality to collect the required information as well as familiarity among PBMs that will be submitting such information. In accordance with section 1860D–12(h)(5)(A) of the Act, as added by the CAA, we will specify standard, machine-readable formats for PBMs to submit annual reports no later than June 1, 2027. Section 6224(a)(3) of the CAA specifies that the implementation of this subsection is not subject to the Paperwork Reduction Act. In accordance with section 1860D–12(h)(5)(B) of the Act, we intend to release this machine-readable format via program instruction.

Section 1860D–12(h)(1)(C)(i)(XI) of the Act describes a summary document submitted in a standardized template developed by the Secretary that includes such information described in section 1860D–12(h)(1)(C)(i)(I) through section 1860D–12(h)(1)(C)(i)(X). We propose at § 423.2814(e) that this document be the annual report in the machine-readable format referenced in the previous paragraph. We propose at § 423.2814(f) that the annual report be certified by the Chief Executive Officer, Chief Financial Officer, or General Counsel of such PBM, or an individual delegated the authority to sign on behalf of these officers, who reports directly to the officer.

For the purposes of describing the data at section 1860D–12(h)(1)(C) of the Act, CMS proposes to adopt the following definitions at § 423.2814(c).

a. General

For purposes of collecting the data described at section 1860D–12(h)(1)(C)(i) of the Act, CMS proposes the following definitions:

- *30-day supply* means the amount of such drug equal to the average 30-day equivalent supply, as described at § 423.104(d)(2)(iv)(A)(2), across all PDE records for such drug for enrollees in such plan in such plan year. If the PBM does not have access to PDE records for such plan for such plan year, an estimated amount per 30-day supply based on dosage information on the most recent label approved by the Food and Drug Administration (FDA) or other reasonable assumptions may be used.

- *Affiliate* has the meaning proposed at § 423.2802.

- *Dosage unit* means the amount of such drug represented by its National Council for Prescription Drug Programs (NCPDP) unit type.

- *Drug* means a drug or biological product associated with a unique NDC–11 or NDC–12 identifier.

- *Generic or non-proprietary name* means the name that matches the nonproprietary name data element in the NDC Directory product file.

- *National Drug Code* means the unique, eleven-digit or twelve-digit identifier of the NDC submitted by the Food and Drug Administration to the Drug Registration and Listing System for a drug product, also known as an NDC–11 or NDC–12 code.

- *Pharmacy benefit manager* has the meaning described at § 423.2802.

b. List of Drugs

For purposes of collecting the data described at section 1860D–12(h)(1)(C)(i)(I) of the Act, CMS proposes the following definitions:

- *Average National Average Drug Acquisition Cost (NADAC)*: the sum of the products of each NADAC in effect for such drug during such plan year and the quotient of the number of days in which such NADAC was in effect divided by the number of days any NADAC was in effect during such year.

- *Average pharmacy reimbursement amount paid by the plan for the drug* means the average of the amount paid by the plan per 30-day supply of the drug, across all fills of the drug during such plan year.

- *Average wholesale acquisition cost* means the sum of the products of each wholesale acquisition cost (WAC) in effect for such drug during such plan year and the quotient of the number of days in which such WAC was in effect divided by the number of days any WAC was in effect during such year.

- *Average wholesale price* means the sum of the products of each average wholesale price (AWP) in effect for such drug during such plan year and the quotient of the number of days in which such AWP was in effect divided by the number of days any AWP was in effect during such year.

- *Day's supply* means the amount of such drug represented by the average day's supply across all fills in PDE data for such drug for such Part D plan sponsor and PBM in such plan year. If the PBM does not have access to PDE data, an estimated amount per day's supply based on dosage information on the most recent label approved by the Food and Drug Administration (FDA) or other reasonable assumptions may be used.

- *Dispensing channel* means the dispensing channel as represented by the NCPDP pharmacy dispenser type code. If there are multiple NCPDP pharmacy dispenser type codes, the

beneficiary's residence type should be used to determine the appropriate dispensing channel.

- *Total manufacturer-derived revenue, inclusive of bona fide service fees, attributable to the drug and retained by the pharmacy benefit manager and any affiliate of such pharmacy benefit manager* means revenue that is either (a) paid directly from a manufacturer to the PBM or affiliate or (b) paid directly from a manufacturer to any entity and passed through in whole or in part from that entity, as well as from any other additional entities, and is received by the PBM or affiliate. Only the amount of revenue received by the PBM and any affiliate of such PBM should be included in this amount; revenue retained by other entities and not passed through should not be included.

- *Typical course of treatment* means the amount of such drug estimated by the PBM to be associated with a typical course of treatment based on dosage information on the most recent label approved by the Food and Drug Administration (FDA), using reasonable assumptions for variable factors such as patient weight or other factors affecting dosing, which must be reported by PBMs as part of the data submission. For drugs or biological products used to treat chronic conditions for which the typical course of treatment is indefinite, the typical amount of such drug associated with 1 year of treatment may be used, and PBMs must indicate this methodology in the reasonable assumptions.

c. Pharmacy Information

For purposes of collecting the data described at section 1860D–12(h)(1)(C)(i)(II) of the Act, CMS proposes the following definitions:

- *90-day supply* means three times the 30-day supply of the drug, as defined under § 423.2814(c).

- *Affiliate, such as a pharmacy or other entity that acquires prescription drugs, that initially acquires the drug* means an affiliate that, during any point in the plan year, acquired any amount of the drug that had not previously been acquired by an affiliate of the same PBM (or, in the event that the manufacturer of the drug is an affiliate of the PBM and sold the drug to another affiliate of the same PBM, such affiliate that acquired the drug from such manufacturer). If multiple affiliates meet such criteria, all such affiliates must be treated as the affiliate that initially acquires the drug, and the acquisition cost must be averaged across all such affiliates. If an entity was an affiliate of the PBM for only a portion of the plan year, that

entity shall be considered the affiliate that initially acquires the drug if, after the day on which it becomes an affiliate during the plan year, it acquires the drug earlier than any other affiliate or acquires the drug from an affiliate manufacturer.

- *Average acquisition cost* means the average cost, per dosage unit, to the entity to acquire the drug, from all sources from which such entity acquired the drug during such plan year, both in aggregate and by dispensing channel.

- *Course of treatment* has the meaning of “typical course of treatment” defined at § 423.2814(c).

- *Percentage of total prescriptions that were dispensed by pharmacies that are an affiliate of the pharmacy benefit manager for each drug* means the quotient of the number of 30-day supplies of such drug (as defined at § 423.2814(c)) dispensed by pharmacies that are an affiliate of the PBM to an enrollee of such Part D plan sponsor in such plan year divided by the number of 30-day supplies of such drug dispensed by any pharmacy to an enrollee of such Part D plan sponsor in such plan year.

- *Pharmacy network* means the pharmacy network inclusive of both preferred and non-preferred pharmacies.

d. Reference Listed Drugs and Generics

For purposes of collecting the data described at section 1860D–12(h)(1)(C)(i)(III) of the Act, CMS proposes the following definitions:

- *Currently marketed generic drug* means a generic drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act that meets either of the following criteria: is listed in the Orange Book and is not discontinued, or is listed in the product file of the National Drug Code Directory with either a blank end marketing date or an end marketing date in the future.

Additionally, we recognize that this segment of data elements elicits information about the degree to which formulary tier placement decisions and utilization management tools treat brand name drugs more favorably than generics. However, additional information beyond the data elements explicitly enumerated in section 1860D–12(h)(1)(C)(i)(III) of the Act would provide a more meaningful understanding of these plan design features and better enable compliance efforts by Part D plan sponsors and CMS. For example, while section 1860D–12(h)(1)(C)(i)(III) of the Act requires PBMs to estimate and report what beneficiary cost-sharing for a 30-day supply of generic drugs that are

placed on a formulary tier typically associated with higher cost-sharing than their listed drug would have been had they been placed on the same formulary tier as the listed drug, the statute did not require PBMs to report what actual beneficiary cost-sharing was for such generic drugs. The estimates of beneficiary cost-sharing if the generic drug had been on a different formulary tier would have significantly more meaning if Part D plan sponsors and CMS were able to compare them to actual cost-sharing for that same generic drug. Similarly, while section 1860D–12(h)(1)(C)(i)(III) of the Act requires that PBMs report on whether generic drugs are “covered on the same formulary tier or a formulary tier typically associated with higher cost-sharing than the listed drug, or are subject to utilization management that the listed drug is not subject to”, it only solicits additional information on the formulary tier portion of that phrase—via information about the effects on beneficiary cost-sharing—but not additional information on the effects of other utilization management tools. We believe that greater insight into the outcomes of utilization management tools—rather than information merely about their existence—would better allow Part D plan sponsors and CMS to understand the degree to which the listed drug is or is not being treated more favorably than its generics in practice. Finally, due to potential differences in treatment of generic drugs or biosimilars that are private label vs. non-private label, we propose to collect information separately for private label vs. non-private label generic drugs and biosimilars.

Consistent with our authority under sections 1860D–12(b)(3)(D) and (h)(1) of the Act, we are proposing to add the following data elements to the reporting requirements at § 423.2814(d)(3):

- Whether each generic drug described at § 423.2814(d)(3)(i) is private label or not.
- Where a currently marketed generic drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an application that references such listed drug is on a formulary tier typically associated with higher cost-sharing than the listed drug, the average beneficiary cost-sharing under the plan for a 30-day supply of each such generic drug.
- Where the listed drug is subject to prior authorization under the plan, the average denial rate of prior authorizations submitted for the listed drug during the plan year.
- Where a currently marketed generic drug approved under section 505(j) of

the Federal Food, Drug, and Cosmetic Act pursuant to an application that references such listed drug is subject to prior authorization under the plan, the average denial rate of prior authorizations submitted for each such generic drug during the plan year.

- Where the listed drug is subject to any utilization management tool other than prior authorization under the plan, a brief description of each such utilization management tool.
- Where the listed drug is subject to any utilization management tool other than prior authorization, the average denial rate of each such utilization management tool during the plan year.
- Where a currently marketed generic drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an application that references such listed drug is subject to the same utilization management tool (other than prior authorization) as the listed drug, the average denial rate of each such utilization management tool during the plan year.

e. Reference Products and Biosimilars

For purposes of collecting the data described at section 1860D–12(h)(1)(C)(i)(IV) of the Act, CMS proposes the following definitions:

- *Currently marketed biosimilar biological product* means a biosimilar biological product licensed under section 351(k) of the Public Health Service Act that meets either of the following criteria: is listed in the Purple Book with a marketed status of “Rx”, or is listed in the product file of the National Drug Code Directory with either a blank end marketing date or an end marketing date in the future.

Additionally, we propose to add the following data elements to the reporting requirements at § 423.2814(d)(4), in alignment with similar elements proposed to be added to § 423.2814(d)(3):

- Whether each biosimilar biological product described at § 423.2814(d)(4)(i) is private label or not.
- Where a currently marketed biosimilar biological product licensed under section 351(k) of the Public Health Service Act pursuant to an application that refers to such reference product is on a formulary tier typically associated with higher cost-sharing than the reference product, the average beneficiary cost-sharing under the plan for a 30-day supply of each such biosimilar biological product.
- Where the reference product is subject to prior authorization under the plan, the average denial rate of prior authorizations submitted for the reference product during the plan year.

- Where a currently marketed biosimilar biological product licensed under section 351(k) of the Public Health Service Act pursuant to an application that refers to such reference product is subject to prior authorization under the plan, the average denial rate of prior authorizations submitted for each such biosimilar biological product during the plan year.

- Where the reference product is subject to any utilization management tool other than prior authorization under the plan, a brief description of each such utilization management tool.

- Where the reference product is subject to any utilization management tool other than prior authorization, the average denial rate of each such utilization management tool for the reference product during the plan year.

- Where a currently marketed biosimilar biological product licensed under section 351(k) of the Public Health Service Act pursuant to an application that refers to such reference product is subject to the same utilization management tool (other than prior authorization) as the listed drug, the average denial rate of each such utilization management tool for each such biosimilar biological product during the plan year.

f. Revenue Retained by the Pharmacy Benefit Manager

For purposes of collecting the data described at section 1860D–12(h)(1)(C)(i)(VI) of the Act, CMS proposes the following definitions:

- *Remuneration related to utilization of Part D drugs* means remuneration that meets the requirements at § 423.2810(h).

g. Broker, Consultant, Advisors, and Auditors

For purposes of collecting the data described at section 1860D–12(h)(1)(C)(i)(IX) of the Act, CMS proposes the following definitions:

- *Pharmacy benefit management services* has the meaning of “PBM function” described at § 423.2802.

We solicit comment on these proposed definitions, as well as whether there are other terms related to the annual reporting requirement that warrant further definition.

Note that section 1860D–12(h)(1) of the Act requires that Part D plan sponsors have a written agreement with the PBM under which the PBM, and any affiliates of such PBM as applicable, agree to meet requirements including the data reporting requirements at section 1860D–12(h)(1)(C) of the Act; as such, failure to comply with this requirement in the written agreement between the Part D plan sponsor and the

PBM may result in the Part D plan sponsor being subject to a CMP as authorized under section 1860D–12 of the Act and 42 CFR 423.752. Compliance with the data reporting requirements includes providing complete and accurate information and responding to inquiries to clarify, correct, or supplement the submission, including as necessary to allow CMS to confirm the full accuracy and completeness of the required information.

9. Written Explanation of Contracts or Agreements With Manufacturers

Section 1860D–12(h)(1)(C)(iii) of the Act, as added by the CAA, provides that not later than 30 days after the finalization of any contract or agreement between a PBM or an affiliate of such PBM and a manufacturer (or subsidiary, agent, or entity affiliated with such manufacturer) that makes rebates, discounts, payments, or other financial incentives related to one or more covered Part D drugs or other prescription drugs, as applicable, of the manufacturer directly or indirectly contingent upon coverage, formulary placement, or utilization management conditions on any other covered Part D drugs or other prescription drugs, as applicable, such PBM shall submit to the Part D plan sponsor a written explanation of such contract or agreement. It further specifies that such written explanation shall include the manufacturer subject to the contract or agreement, all covered Part D drugs and other prescription drugs, as applicable, subject to the contract or agreement and the manufacturers of such drugs, and a high-level description of the terms of such contract or agreement and how such terms apply to such drugs. We propose to adopt these requirements at § 423.2816(a).

Further, we propose at § 423.2816(c) that the high-level description of the terms of such contract or agreement describe the methodology by which the rebates, discounts, payments, or other financial incentives related to one or more Part D drugs or other prescription drugs is directly or indirectly contingent on coverage, formulary placement, or utilization management conditions on any other Part D drugs or other prescription drugs. We solicit comment on whether we should apply additional requirements to the written explanation, and in particular whether there are standardized fields or types of information that should be required.

Section 1860D–12(h)(1)(C)(iii)(II)(bb) of the Act also provides that such written explanation be certified by the Chief Executive Officer, Chief Financial

Officer, or General Counsel of such PBM, or affiliate of such PBM, as applicable, or an individual delegated the authority to sign on behalf of one of these officers, who reports directly to the officer. We propose to adopt this requirement at § 423.2816(d).

Finally, 1860D–12(h)(1)(C)(iii)(III) of the Act defines the term “other prescription drugs” as “prescription drugs covered as supplemental benefits under this part or prescription drugs paid outside of this part”. We propose to adopt this definition at § 423.2816(b).

10. Audit Rights

Section 1860D–12(h)(1)(D) of the Act provides that not less than annually, at the request of the Part D plan sponsor, the PBM allow for an audit of the PBM to ensure compliance with all terms and conditions of the written agreement required by section 1860D–12(h)(1) of the Act and the accuracy of data reported under section 1860D–12(h)(1)(C) of the Act. It further provides that the Part D plan sponsor shall have the right to select an auditor and that the PBM shall not impose any limitations on the selection of such auditor. It additionally provides that the PBM shall make available to such auditor all records, data, contracts, and other information necessary to confirm the accuracy of information reported under section 1860D–12(h)(1)(C) of the Act, subject to reasonable restrictions on how such information must be reported to prevent redisclosure of such information. We propose to adopt these requirements at § 423.2818.

We note that while section 1860D–12(h)(1)(D)(i) of the Act describes the audit as encompassing both compliance with all terms and conditions of the written agreement required by section 1860D–12(h)(1) of the Act and the accuracy of data reported under section 1860D–12(h)(1)(C) of the Act, section 1860D–12(h)(1)(D)(iii) of the Act, which describes the information to be provided, only addresses records, data, contracts, and other information necessary to confirm the accuracy of information reported under section 1860D–12(h)(1)(C) of the Act. We do not interpret section 1860D–12(h)(1)(D)(iii) of the Act to mean that PBMs are not required to provide information related to compliance with all terms and conditions of the written agreement required by section 1860D–12(h)(1) of the Act as requested by the auditor. Rather, we interpret it to mean that a PBM may not refuse to provide records, data, contracts, and other information necessary to confirm the accuracy of information reported under section 1860D–12(h)(1)(C) of the Act under the

logic that such PBM has already reported data to the Part D plan sponsor as required under section 1860D–12(h)(1)(C) of the Act. In other words, the reporting of data under section 1860D–12(h)(1)(C) of the Act is not equivalent to reporting sufficient information to support an audit.

However, we do not believe that this clarification suggests that PBMs are not required to provide information related to compliance with all terms and conditions of the written agreement required by section 1860D–12(h)(1) of the Act as requested by the auditor.

Further, we propose at § 423.2818(c)(2) that such reasonable restrictions may address the types of records, data, contracts, and other information to be reported; the manner of reporting such information; and the use, disclosure, and dispensing of such information by the auditor and the Part D plan sponsor. They may not include requirements that wholly prevent the auditor from accessing records, data, contracts, and other information that are necessary to confirm the accuracy of information reported under section 1860D–12(h)(1)(C) of the Act.

Section 1860D–12(h)(1)(D)(iv) of the Act provides that the PBM must provide such information and other information, data, and records relevant to the audit to such auditor within 6 months of the initiation of the audit and respond to requests for additional information from such auditor within 30 days after the request for additional information. We propose to adopt this requirement at § 423.2818(d).

Finally, section 1860D–12(h)(1)(D)(v) of the Act provides that the PBM shall be responsible for providing to such auditor information required to be reported under proposed § 423.2814 or under § 423.2818(c) that is owned or held by an affiliate of such PBM. We propose to adopt this requirement at § 423.2818(e).

11. Compliance and Enforcement

a. Disgorgement of Fees to CMS

Section 1860D–12(h)(2) of the Act, as added by the CAA, introduces certain enforcement mechanisms. Section II.C.e.6. of this proposed rule describes our proposal at § 423.2810(g) to: (1) require PBMs or affiliates of such PBMs to disgorge to Part D plan sponsors any remuneration paid to such PBMs or an affiliate of such PBMs in violation of the requirements described at § 423.2810(a) no later than the earlier of the following dates: 30 days following the conclusion of an audit by the Part D plan sponsor, as allowed at § 423.2818, through which remuneration paid to the pharmacy

benefit manager or affiliate of such pharmacy benefit manager in violation of the requirements described at § 423.2810(a) was found; or 30 days following the end of the month in which the pharmacy benefit manager or affiliate of such pharmacy benefit manager identifies remuneration paid to the pharmacy benefit manager or affiliate of such pharmacy benefit manager in violation of the requirements at § 423.2810(a); and (2) require that the PBMs or affiliate of such PBMs must provide the following information to the Part D plan sponsor: the amount of the remuneration in violation of the requirements described at § 423.2810(a), the entity from which such remuneration derived, the entity that received such remuneration, and the nature of the violation.

Under section 1860D–12(h)(1)(A) of the Act, each Part D plan sponsor must disgorge to the Secretary any amounts disgorged to the Part D plan sponsor by a PBMs or affiliate of such PBMs under § 423.2810(g). In order to effectuate this requirement, CMS proposes at § 423.2820(a), to utilize the information reported pursuant to the requirements proposed at § 423.2814(d)(11) to recoup such funds from Part D plan sponsors for deposit in the Federal Supplementary Medical Insurance (SMI), or Part B and D, Trust Fund. CMS would utilize our regular payment processes we engage in with Part D plan sponsors to make a payment adjustment to relevant Part D plan sponsors, as applicable, within the quarter (three months) that starts on the July 1 data submission deadline at § 423.2814(a). We note that this proposed timeline may result in variable timeframes for disgorgement of funds to CMS, specifically in situations where an audit uncovers a violation or a PBM or affiliate of such PBM identifies remuneration paid to the pharmacy benefit manager or affiliate of such pharmacy benefit manager in violation of the requirements at § 423.2810(a) and disgorges the remuneration in violation to the Part D plan sponsor months prior to when the information must be reported to CMS (by July 1 of each year), and then disgorged to CMS. However, we believe this proposed timeframe is reasonable, given our proposed annual timeframe for reporting mechanisms for PBMs, and that we need to ensure appropriate oversight and transparency from PBMs with regard to disgorged funds prior to processing payment adjustments from the Part D plan sponsors for such funds. In addition, we will monitor the volume and frequency of funds disgorged (from PBMs or

affiliates of such PBMs to Part D plan sponsors and then to CMS) and may consider alternative timelines for future reporting years if reasonable. We seek comment on our proposed timeline for disgorgement to CMS of remuneration in violation of the proposed requirements at § 423.2810, including whether we should consider a shorter timeframe for collecting monies from Part D plan sponsors. We propose to adopt this requirement at § 423.2820(a).

b. Civil Money Penalty Pass-Through

Section 1860D–12(h)(2)(A)(ii) of the Act provides that each Part D plan sponsor shall require, in a written agreement with any PBM acting on behalf of such sponsor or affiliate of such PBM, that such PBM or affiliate of such PBM reimburse the Part D plan sponsor for any civil money penalty (CMP) imposed on the Part D plan sponsor as a result of the failure of the PBM or affiliate to meet the requirements of section 1860D–12(h)(1) of the Act that are applicable to the PBM or affiliate under the agreement. We propose to adopt this requirement at § 423.2820(b).

The CAA did not introduce new authority for CMS to issue CMPs. Therefore, any such CMPs would be issued under CMS' existing authority at section 1857(g) of the Act, also referenced in section 1860D–12 of the Act, and the implementing regulations at 42 CFR 423 Subpart O.

c. Punitive Remedies for Breach of Contract Between Part D Plan Sponsor and PBM

Section 1860D–12(h)(2)(A)(iii) of the Act provides that each Part D plan sponsor shall require, in a written agreement with any PBM acting on behalf of such sponsor or affiliate of such PBM, that such PBM or affiliate be subject to punitive remedies for breach of contract for failure to comply with the requirements applicable under section 1860D–12(h)(1) of the Act. We propose to adopt this requirement at § 423.2820(c). We solicit comment on whether CMS should specify the types of punitive remedies that should be included in such written agreements.

d. Reporting of Alleged Violations, Anti-Retaliation, and Anti-Coercion

Section 1860D–12(h)(2)(B) of the Act provides that the Secretary shall make available and maintain a mechanism for manufacturers, Part D plan sponsors, pharmacies, and other entities that have contractual relationships with PBMs or affiliates of such PBMs to report, on a confidential basis, alleged violations of the requirements at section 1860D–

12(h)(1)(A) and section 1860D–12(h)(1)(C) of the Act. We propose to adopt this requirement at § 423.2820(d). Reporting of such alleged violations will be made possible in a form and manner specified by CMS.

Section 1860D–12(h)(2)(B) of the Act further specifies that consistent with applicable Federal or State law, a Part D plan sponsor shall not retaliate against an individual or entity for reporting an alleged violation as described previously; or coerce, intimidate, threaten, or interfere with the ability of an individual or entity to report any such alleged violations. We propose to codify this requirement at § 423.2820(e).

e. Certificate of Compliance

Section 1860D–12(h)(3) of the Act provides that each Part D plan sponsor shall furnish to the Secretary (at a time and in a manner specified by the Secretary) an annual certification of compliance with section 1860D–12(h) of the Act, as well as such information as the Secretary determines necessary to carry out this subsection. We propose at § 423.2820(f) to collect this annual certification in a form and manner specified by CMS. We anticipate collecting this annual certification through the HPMS as part of the annual contract cycle that occurs prior to open enrollment for a subsequent plan year. Under this proposal, Part D plan sponsors would furnish the first certification of compliance in the third quarter of calendar year 2027 to attest to compliance in plan year 2028.

12. Confidentiality and Use of Information

Section 1860D–12(h)(6) of the Act requires that information disclosed by a PBM, an affiliate of a PBM, a Part D plan sponsor, or a pharmacy under section 1860D–12(h) of the Act that is not otherwise publicly available or available for purchase shall not be disclosed by the Secretary or a Part D plan sponsor receiving the information, except that the Secretary may disclose the information for the following purposes: as the Secretary determines necessary to carry out Part D of Title XVIII of the Act; to permit the Comptroller General to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; to permit the Executive Director of the Medicare Payment Advisory Commission to review the information provided; to the Attorney General for the purposes of conducting oversight and enforcement; or to the Inspector General of the Department of Health and Human Services in

accordance with its authorities under the Inspector General Act of 1978 (section 406 of title 5, United States Code), and other applicable statutes. We propose to adopt these requirements at § 423.2822(b).

We propose at § 423.2822(a) to define “available for purchase” as available: (1) in exchange for remuneration; and (2) through an agreement for which the purpose is the provision of such information. For example, WACs available through third party compendia such as First Databank, Medi-Span, or Red Book would meet these criteria since users must pay for access to these data, and the purpose of such payment is to access the data. Conversely, information on price concessions negotiated by a rebate aggregator would not meet these criteria because, while a PBM may gain access to such information via a contract with the rebate aggregator for the rebate aggregator’s negotiation services, the purpose of such a contract would be for negotiation rather than the provision of such information. We intend for this policy to treat as confidential information that may be disclosed incidentally between contracting parties but which is not otherwise available for purchase.

Section 1860D–12(h)(6) of the Act requires that the Secretary, the Comptroller General, the Director of the Congressional Budget Office, and the Executive Director of the Medicare Payment Advisory Commission not report on or disclose the information described previously in this section (section II.C.12. of this proposed rule) to the public in a manner that would identify a specific PBM, affiliate,

pharmacy, manufacturer, wholesaler, Part D plan sponsor, or plan; or contract prices, rebates, discounts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. We propose to adopt these requirements at § 423.2822(c).

We solicit comment on these proposals.

13. Severability

The Modernizing and Ensuring Pharmacy Benefit Manager Accountability provisions proposed herein at § 423.2800 through § 423.2822 are separate and severable from one another. If any of these provisions, once finalized, is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it is our intention that such provision would be severable from this rule and not affect the remainder thereof, or the application of such provision to other persons not similarly stated or to other, dissimilar circumstances. For example, if finalized, should the requirements for the timing of the disgorgement of fees proposed herein be deemed invalid or unenforceable, the underlying obligation under current statute would continue.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a “collection of information,” as defined under 5 CFR

1320.3(c) of the PRA’s implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain confirmed or potential collection of information requirements. Comments, if received, will be addressed in the subsequent final rule (CMS–4214–F).

A. Wage Data

To derive average (mean) costs, we are using data from the most current U.S. Bureau of Labor Statistics’ (BLS’s) National Occupational Employment and Wage Estimates for all salary estimates (<https://data.bls.gov/oes/#/area/0000000/2025>), which, at the time of publication of this proposed rule, provides May 2025 wages. In this regard, Table III.1 presents BLS’s mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE III.1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupational Title	Occupational Code	Mean Hourly Wage (\$/hr)	Cost of Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Wage (\$/hr)
Business Operations Specialists, All Other	13-1199	45.18	45.18	90.36
Compensation and Benefits Managers	11-3111	78.19	78.19	156.38
Compliance Officers	13-1041	42.50	42.50	85.00
Computer Programmers	15-1251	50.56	50.56	101.12
Computer Support Specialists	15-1230	33.55	33.55	67.10
Computer Systems Analysts	15-1211	55.10	55.10	110.20
Financial Managers	11-3031	89.86	89.86	179.72
General and Operations Managers	11-1021	64.87	64.87	129.74
Human Resources Managers	11-3121	78.96	78.96	156.38
Insurance Claims and Policy Processing Clerks	43-9041	25.44	25.44	50.88
Lawyers	23-1011	89.35	89.35	178.70
Medical and Health Services Managers	11-9111	67.77	67.77	135.54
Software Developers	15-1252	71.20	71.20	142.40

Adjusting our employee hourly wage estimates by a factor of 100 percent is a rough adjustment that is being used since fringe benefits and other indirect costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. In this regard, we believe that doubling the hourly wage to estimate costs is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within this proposed rule.

1. ICRs Regarding REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026) (§§ 422.2, 422.111, 422.123, and 422.124)

The following proposed changes will be submitted to OMB under control number 0938–10981 (CMS–TBD). At this time the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. The control number's expiration date will be issued by OMB upon their approval of our final rule's collection of information request.

We are proposing several requirements related to the REAL Health Providers Act, which is part of section 6220 of the Consolidated Appropriations Act, 2026, effective for contract year 2028. Topics in this proposal include provider directory verification, updating, accuracy analysis, accuracy scoring, reporting, public transparency, enrollee cost sharing protections, and disclosure. Through these proposed codifications implementing the REAL Health Providers Act, CMS seeks to promote provider directory accuracy and accountability among MA organizations to ensure that beneficiaries are provided with clear, accurate information on the network of providers available to meet their health care needs.

a. ICRs Regarding Provider Directory Verification, Updating, and Disclosure (§§ 422.2, 422.123(b) Through (c) and 422.111(b)(12) and (k)(6))

CMS's proposed provider directory verification requirements (§ 422.123(b)) would require MA organizations to verify the provider directory information of each provider listed in a

specified MA plan's provider directory at least every 90 days, or every 12 months for specified hospitals and facilities, using one or more CMS-specified verification methods. Provider directory information that cannot be verified would be identified in the provider directory as potentially out of date. Proposed § 422.123(b)(4) would also require MA organizations to include a new contract term obligating contracted providers to maintain current and accurate provider directory information. CMS's proposed provider directory updating requirements at § 422.123(c) would retain the existing 30-day update standard, require a quarterly addendum containing updates for all enrollees who requested physical hardcopy directories, require a disclaimer on physical hardcopy provider directories directing beneficiaries to the online provider directory or the MA organization for the latest updates, and require removal of non-contracted providers within 5 business days. Proposed disclosure requirements at §§ 422.111(b)(12) and (k)(6) would require provider directory disclosures regarding cost sharing protections and the accuracy score, as well as a cost sharing protection notice in the first EOB of each plan year.

For most of the proposed provider directory changes, CMS expects that MA organizations would build upon existing provider directory processes rather than develop entirely new processes. Existing § 422.111(b)(3)(i) requires MA organizations to disclose the number, mix, and distribution of providers from whom enrollees may reasonably be expected to obtain services and each provider's cultural and linguistic capabilities. Existing § 422.111(m), finalized in the September 2025 final rule (90 FR 45140), further requires MA organizations to make the information described in § 422.111(b)(3)(i) available to CMS/HHS for publication in MPF, update that information within 30 days after becoming aware of a change, and attest to its accuracy at least annually. The information collection for these MPF submission, formatting, and attestation requirements is approved under OMB control number 0938–1491 (CMS–10906).

As CMS explained in the September 2025 final rule, CMS's operational guide would specify how MA organizations must format and submit provider directory data, and the current

Technical Implementation Guide identifies data points used for MPF, including provider or facility NPI and name, specialty or facility type, MA plan identifier, address, telephone number, practitioner languages, and whether a practitioner is accepting new patients. Existing provider directory content is also specified in the Medicare Advantage and Section 1876 Cost Plan Provider Directory Model and Instructions. For example, the model requires provider name, specialty, address, telephone number, cultural and linguistic capabilities, and information identifying whether providers are accepting new patients or directing beneficiaries to contact the provider. The model also addresses accessibility restrictions and telehealth capabilities. Therefore, the proposed definition of “provider directory information” at § 422.2 largely consolidates and standardizes information already addressed through existing provider directory requirements and guidance, including provider name, specialty, contact information, address, accepting new patients status, accommodations for people with disabilities, cultural and linguistic capabilities, and telehealth capabilities.

We are also proposing to add “common ownership or control disclosure” as a provider directory information element at § 422.2. Because this information is not part of the existing MPF provider directory data submission, CMS preliminarily estimates that it would take an MA organization 1.5 hours at \$90.36/hr for a business operations specialist to identify applicable ownership or common-control relationships. With 708 contracts, CMS estimates an annual burden of 1,062 hours (708 MA organization contracts × 1.5 hr/response) at a cost of \$95,962 (1,062 hr × \$90.36/hr). CMS assumes MA organizations would use ownership and affiliation information they already maintain. If they need to confirm this information with a provider, that time would be included in the verification burden discussed later in this section. CMS seeks comments on these assumptions, including the time needed to identify, maintain, verify, and disclose ownership/affiliation information and whether MA organizations or providers would incur additional burden.

TABLE III.2: ESTIMATE FOR INCLUSION OF COMMON OWNERSHIP OR CONTROL DISCLOSURE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost(\$)
§ 422.2	708 MA organizations	708	1.5	1,062	90.36	95,962

CMS believes that some routine administrative activities associated with maintaining provider directory information may qualify as usual and customary business practices under 5 CFR 1320.3(b)(2) and, therefore, may be exempt from review by OMB under the authority of the PRA of 1995 (44 U.S.C. 3501 *et seq.*). However, CMS would assess any additional burden resulting from proposed requirements that go beyond existing practices. Although the data elements contained within the proposed definition of “provider

directory information” at § 422.2 largely overlap with existing provider directory requirements and guidance, CMS would consider burden associated with any expansion in the information required and, in particular, changes to the frequency and manner of verification, updating, disclosure, or submission.

The proposed verification requirements may also impose burden on contracted providers. Proposed § 422.123(b)(4) would require MA organizations to include a new contract term obligating contracted providers to

maintain current and accurate provider directory information. Because this is a new contractual requirement, CMS does not consider the burden associated with modifying existing provider contracts to be covered by the usual and customary business practice exemption. CMS estimates a one-time burden of 3 hours per MA organization contract to add the new proposed contract term. Across 708 contracts, this results in a one-time burden of 2,124 hours (708 contracts × 3 hr) at a cost of \$191,925 (2,124 hr × \$90.36/hr).

TABLE III.3: ESTIMATE FOR UPDATING PROVIDER CONTRACTS

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost(\$)
§ 422.123(b)(4)	708 MA organizations	708	3	2,124	90.36	191,925

The proposed provider directory verification activities of MA organizations under § 422.123(b)(2) may also require providers to review, confirm, correct, or attest to provider directory information. To estimate the additional burden from recurring verification, CMS assumes each direct verification contact would take about 15 minutes for the provider and 15 minutes for the MA organization. This would result in up to 1 hour annually for providers verified every 90 days and 15 minutes annually for specified hospitals and facilities verified every 12 months. These estimates exclude verification using existing plan information or CMS-maintained data sources. We seek comments on these assumptions, including the frequency of direct provider contacts, time required, verification methods used, and the extent to which these activities exceed current practices.

Proposed § 422.123(c)(4)(i) would also require MA organizations to remove a provider from the provider directory no later than 5 business days after determining that the provider is no longer participating in the specified MA plan’s network, rather than under the existing 30-day update standard. CMS

estimates that meeting the shorter timeframe would add about 15 minutes of administrative work for each provider removal. CMS cannot estimate the total burden because it does not know how many providers are removed each year or how many MA organizations already meet the 5-business day timeframe. We seek comments on these assumptions, including the number of removals, current practices, and the time and cost needed to meet the proposed requirement.

b. ICRs Regarding Provider Directory Accuracy Analysis and Accuracy Score (§ 422.123(d)(1) Through (4))

At § 422.123(d)(1) through (4), CMS is proposing new requirements for MA organizations offering specified MA plans to conduct an annual provider directory accuracy analysis for each specified MA plan using a random sample of provider directory listings, including providers with provider specialty types with high provider directory inaccuracy rates, and to estimate an annual provider directory accuracy score based on such analysis. Although the proposed requirements would add some new burden for MA organizations, the requirements are

designed to build upon the existing provider directory framework.

For each specified MA plan, MA organizations would use a random sample consisting of 65 percent of records in the provider directory, excluding records for providers with provider specialty types with high provider directory inaccuracy rates, and 35 percent of records for providers with provider specialty types with high provider directory inaccuracy rates, using the sampling methodology specified by CMS.

MA organizations would verify provider directory data elements for sampled providers using CMS’s specified verification methods, subject to any applicable limitations on the methods that may be used to verify each provider directory element for purposes of calculating the accuracy score. Following verification, for each specified MA plan, MA organizations would calculate the accuracy percentage for each scored provider directory element, apply the applicable provider directory element weight, combine the weighted results to calculate the final composite score, and round the result to the nearest whole number to determine the final provider directory accuracy

score, in accordance with the scoring methodology specified by CMS.

CMS estimates the burden for the annual provider directory accuracy analysis and accuracy score based on the number of specified MA plans offered under an MA parent

organization. CMS used available 2026 data to estimate the number of specified MA plans and the number of MA parent organizations in each grouping. For MA parent organizations with 10 or fewer specified MA plans, CMS estimates 13

hours per response at \$90.36/hr for a business operations specialist. With 113 respondents, CMS estimates an annual burden of 1,469 hours (113 respondents $\times$ 13 hr/response) at a cost of \$132,739 (1,469 hr $\times$ \$90.36/hr).

TABLE III.4A: ESTIMATE FOR ANNUAL PROVIDER DIRECTORY ACCURACY ANALYSIS AND ACCURACY SCORE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost(\$)
§ 422.123(d)(1)-(4) (10 or fewer specified MA plans)	113 MA parent organizations	113	13	1,469	90.36	132,739

For contracts with 11 to 50 specified MA plans, CMS estimates 20 hours per

response. With 38 respondents, CMS estimates an annual burden of 760 hours

(38 respondents $\times$ 20 hr/response) at a cost of \$68,674 (760 hr $\times$ \$90.36/hr).

TABLE III.4B: ESTIMATE FOR ANNUAL PROVIDER DIRECTORY ACCURACY ANALYSIS AND ACCURACY SCORE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost(\$)
§ 422.123(d)(1)-(4) (11 to 50 specified MA plans)	38 MA parent organizations	38	20	760	90.36	68,674

For contracts with 51 or more specified MA plans, CMS estimates 30 hours per response. With 12

respondents, CMS estimates an annual burden of 360 hours (12 respondents $\times$

30 hr/response) at a cost of \$32,530 (360 hr $\times$ \$90.36/hr).

TABLE III.4C: ESTIMATE FOR ANNUAL PROVIDER DIRECTORY ACCURACY ANALYSIS AND ACCURACY SCORE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost(\$)
§ 422.123(d)(1)-(4) (51 or more specified MA plans)	12 MA parent organizations	12	30	360	90.36	32,530

The estimated hours reflect that MA parent organizations with more specified MA plans would have an increasing amount of effort, including developing plan-level samples, calculating plan-level scores, and performing quality assurance. CMS assumes that all MA parent organizations would consolidate samples across the organization and would not need to repeat verification when the same record appears in multiple plan samples, which would lower the burden for the MA parent organization as they would only need to verify the record once and could count that verification in the calculation of

each of the plan accuracy scores where the record appears. As the number of specified MA plans that an MA parent organization has increases, CMS assumes that MA parent organizations would develop efficiencies related to developing plan-level samples and calculating plan-level accuracy scores, limiting the overall burden associated with these activities for each additional plan. We seek comments on these burden estimates and assumptions used, including the time required to develop the plan-level sample, conduct the accuracy analysis, and calculate plan-level accuracy scores. CMS also seeks comments on the groupings based on

the number of plans an MA parent organization has and whether the cut points for the groupings represent reasonable burden estimates for each grouping.

Because certain sampling, verification, and scoring requirements remain subject to comment and finalization, the burden estimate may change. Final decisions on sample size and timing, verification requirements, and the scoring methodology could affect the amount and complexity of work required to complete the provider directory accuracy analysis. We may revise the burden estimate based on comments received and the finalized

requirements. The burden estimate may also need to account for finalized requirements concerning provider non-response, use of additional permitted verification methods, replacement records, minimum response rates, and sample size parameters.

c. ICRs Regarding Provider Directory Accuracy Report (§ 422.123(d)(5))

At § 422.123(d)(5), CMS is proposing that MA organizations offering specified MA plans must submit to CMS an annual provider directory accuracy report containing the results of the accuracy analysis and the provider directory accuracy score for each specified MA plan. CMS is proposing that the report must be submitted not

later than the first Monday in April of the year following the contract year being measured, in a form and manner specified by CMS. As proposed, CMS would require that for each specified MA plan, MA organizations must compile the results of the provider directory accuracy analysis and accuracy score and submit the annual provider directory accuracy report to CMS in the required form and manner. These activities may include confirming the accuracy score calculation, reconciling or resolving identified data issues, performing necessary quality assurance, and preparing the information for submission. The scope of this burden may vary depending on

the reporting elements ultimately required by CMS.

CMS estimates the burden for the annual provider directory accuracy report based on the number of specified MA plans offered under an MA parent organization. CMS used available 2026 data to estimate the number of specified MA plans and the number of MA parent organizations in each grouping. For MA parent organizations with 10 or fewer specified MA plans, we estimate 8 hours per response at \$90.36/hr for a business operations specialist. With 113 respondents, we estimate an annual burden of 904 hours (113 respondents × 8 hr/response) at a cost of \$81,685 (904 hr × \$90.36/hr).

TABLE III.5A: ESTIMATE FOR ANNUAL PROVIDER DIRECTORY ACCURACY REPORT

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost (\$)
§ 422.123(d)(5) (10 or fewer specified MA plans)	113 MA parent organizations	113	8	904	90.36	81,685

For MA parent organizations with 11 to 50 specified MA plans, CMS estimates 12 hours per response. With

38 respondents, we estimate an annual burden of 456 hours (38 respondents ×

12 hr/response) at a cost of \$41,204 (456 hr × \$90.36/hr).

TABLE III.5B: ESTIMATE FOR ANNUAL PROVIDER DIRECTORY ACCURACY REPORT

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost (\$)
§ 422.123(d)(5) (11 to 50 specified MA plans)	38 MA parent organizations	38	12	456	90.36	41,204

For MA parent organizations with 51 or more specified MA plans, CMS estimates 18 hours per response. With

12 respondents, we estimate an annual burden of 216 hours (12 respondents ×

18 hr/response) at a cost of \$19,518 (216 hr × \$90.36/hr).

TABLE III.5C: ESTIMATE FOR ANNUAL PROVIDER DIRECTORY ACCURACY REPORT

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost (\$)
§ 422.123(d)(5) (51 or more specified MA plans)	12 MA parent organizations	12	18	216	90.36	19,518

The estimated hours reflect that MA parent organizations with more specified MA plans will have an increasing amount of effort, including compiling plan-level analysis results and accuracy scores, reviewing the

report for completeness and accuracy, performing necessary quality assurance, and preparing to submit the data to CMS. As discussed under section III.B.1.b. of this proposed rule, CMS assumes that MA parent organizations

will develop efficiencies while compiling data for the provider directory accuracy report, limiting the overall burden associated with this activity for each additional plan. CMS seeks comments on these burden

estimates and assumptions used, including the time required to compile analysis results and accuracy scores, review the accuracy report, and submit the accuracy report to CMS. CMS also seeks comments on the groupings based on the number of plans an MA parent organization has and whether the cut points for the groupings represent reasonable burden estimates for each grouping.

We are soliciting comments on the reporting deadline and on elements included in the report that could affect the scope of information compiled and submitted. Therefore, the burden may need to be reconsidered following comment solicitation if the final requirements change the scope or preparation of the report.

In addition, we are considering whether the annual provider directory accuracy report should include additional elements, such as data on the use of cost sharing protections. We are also considering whether to require independent third-party review and certification of the annual provider directory accuracy analysis and

resulting accuracy score before submission to CMS. Because these potential requirements are still under consideration, CMS has not separately calculated the associated burden. If finalized, the current estimate may need to be revised to account for compiling additional data and third-party certification activities.

d. ICRs Regarding Enrollee Cost Sharing Protections When Provider Directories Are Inaccurate (§ 422.124)

CMS is proposing to codify the new requirements at § 422.124 such that beginning with contract year 2028, MA organizations offering specified MA plans will be required to: (1) include a term in each provider contract obligating the provider to supply documentation of the earliest date on which the enrollee's appointment was made; (2) maintain a daily archive of provider directory data for not less than 10 years and make such records available to CMS upon request within 5 business days; (3) process enrollee requests for cost sharing protections as organization determinations or

reconsideration requests; and (4) issue refunds to enrollees when cost sharing is collected in excess of the permitted amount.

Section 422.124(d) would require MA organizations offering specified MA plans to include a term in each provider contract for a specified MA plan obligating the provider to supply documentation of the earliest date on which the enrollee's appointment was scheduled, regardless of any rescheduling. MA organizations would then be required to obtain the scheduling documentation from the provider to determine whether the cost sharing protection applies. To comply with this requirement, each MA organization will need to review its existing provider contracts to incorporate the new contractual language. We estimate that adding the contract provision to each specified MA plan would require 3 hours at \$90.36/hr for a business operations specialist. We estimate a one-time burden of 2,124 hours (708 MA organization contracts × 3 hr) at a cost of \$191,925 (2,124 hr × \$90.36/hr).

TABLE III.6: ESTIMATE FOR UPDATING PROVIDER CONTRACTS

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost 1 st Year (\$)
§ 422.124(d)	708 MA organizations	708	3	2,124	90.36	191,925

Section 422.124(e) would require MA organizations offering specified MA plans to confirm whether the enrollee is eligible for the provider directory cost sharing protection by maintaining and referencing a daily archive of the provider directory sufficient to identify whether a provider was listed in the directory at any time on a given date for not less than 10 years. Additionally, MA organizations would be required to make provider directory records available to CMS upon request within 5

business days. CMS estimates that establishing and maintaining a daily automated archive of provider directory data would require an initial one-time system build and an ongoing annual maintenance burden. MA organizations would need to develop or modify existing IT infrastructure to capture and store a daily snapshot of specified MA plan provider directories in a format sufficient to identify whether a provider was listed on any given date. CMS believes most MA organizations have

existing data warehousing capabilities that could be adapted for this purpose, given other record retention obligations of MA organizations required by CMS.

The one-time system development burden is estimated to take approximately 40 hours at \$142.40/hr for a software developer. CMS estimates a one-time burden of 28,320 hours (708 MA organization contracts × 40 hr) and \$4,032,768 (28,320 hr × \$142.40/hr).

TABLE III.7A: DAILY PROVIDER DIRECTORY ARCHIVE INITIAL SYSTEM DEVELOPMENT ESTIMATE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost (\$)
§ 422.124(e)	708 MA organizations	708	40	28,320	142.40	4,032,768

Ongoing maintenance including storage management, quality checks, and responding to CMS records requests is estimated to take 10 hours at \$142.40/hr for a software developer. CMS

estimates an annual burden of 7,080 hours (708 MA organization contracts × 10 hr) at a cost of \$1,008,192 (7,080 hr × \$142.40/hr). CMS seeks comments on whether these estimates accurately

reflect the operational burden of daily archiving, particularly for smaller MA organizations.

TABLE III.7B: DAILY PROVIDER DIRECTORY ARCHIVE ESTIMATE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost (\$)
§ 422.124(e)	708 MA organizations	708	10	7,080	142.40	1,008,192

Section 422.124 proposes requirements for MA organizations to implement cost sharing protections for items and services furnished based on reliance on incorrect provider directory information. CMS estimates that processing each enrollee request for the cost sharing protection, including verifying the date the appointment was

made, referencing the archived provider directory to confirm whether the provider was listed on that date, making an organization determination, and issuing a notice, would require approximately 1.5 hours at \$90.36/hr for a business operations specialist. We estimate an annual burden of 1,062 hours (708 MA organization contracts ×

1.5 hr) at a cost of \$95,962 (1,062 hr × \$90.36/hr). We note that the volume of anticipated requests is highly uncertain and would depend on the prevalence of provider directory inaccuracies and enrollee awareness of the protections. We seek comments on expected request volumes and whether 1.5 hours is an accurate estimate of processing time.

TABLE III.8: COST SHARING PROTECTION IMPLEMENTATION ESTIMATE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost (\$)
§ 422.124	708 MA organizations	708	1.5	1,062	90.36	95,962

CMS anticipates that contracted providers will incur a burden when the MA organization verifies the date the appointment was made. CMS estimates that each inquiry will require 0.5 hours at \$46.80/hr for an Office and Administrative Support Worker to locate the date an appointment was scheduled and share the information with the MA organization. CMS acknowledges that, due to the absence of reliable data on the total number of contracted providers across all 708 MA organizations and uncertainty around

the number of data requests associated with the cost sharing protection, it is not currently possible to provide a precise aggregate burden estimate. We therefore invite public comments on the estimated number of providers subject to this requirement, the cost, and associated time burden.

In § 422.124(g), we propose to require MA organizations to treat provider directory cost sharing protections as in-network cost sharing for purposes of the MOOP limit consistent with § 422.100(f)(4). We estimate it would

take 0.5 hours at \$90.36/hr for a business operations specialist to process a refund, including the time for calculating the excess amount, issuing payment, and updating MOOP tracking, would require. CMS estimates an annual burden of 354 hours (708 MA organization contracts × 0.5 hr/ response) at a cost of \$31,987 (354 hr × \$90.36/hr). We seek comments on expected request volume and whether 0.5 hours is an accurate estimate to fully process a refund.

TABLE III.9: COST SHARING PROTECTION REFUND ESTIMATE

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost (\$/hr)	Total Annual Cost (\$)
§ 422.124(g)	708 MA organizations	708	0.5	354	90.36	31,987

e. Total Burden: REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026)

Table III.10 summarizes our impacts.

TABLE III.10: ESTIMATED IMPACT OF REAL HEALTH PROVIDERS ACT

Regulatory Section in Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost 1 st Year (\$)	Total Cost Subsequent Years (\$)
§ 422.2	708 MA organizations	708	1.5	1,062	90.36	95,962	95,962
§ 422.123(b)(4)	708 MA organizations	708	3	2,124	90.36	191,925	N/A
§ 422.123(d)(1)-(4) (10 or fewer specified MA plans)	113 MA organizations	113	13	1,469	90.36	132,739	132,739
§ 422.123(d)(1)-(4) (11 to 50 specified MA plans)	38 MA organizations	38	20	760	90.36	68,674	68,674
§ 422.123(d)(1)-(4) (51 or more specified MA plans)	12 MA organizations	12	30	360	90.36	32,530	32,530
§ 422.123(d)(5) (10 or fewer specified MA plans)	113 MA organizations	113	8	904	90.36	81,685	81,685
§ 422.123(d)(5) (11 to 50 specified MA plans)	38 MA organizations	38	12	456	90.36	41,204	41,204
§ 422.123(d)(5) (51 or more specified MA plans)	12 MA organizations	12	18	216	90.36	19,518	19,518
§ 422.124(d)	708 MA organizations	708	3	2,124	90.36	191,925	N/A
§ 422.124(e)	708 MA organizations	708	40	28,320	142.40	4,032,768	N/A
§ 422.124(c)	708 MA organizations	708	10	7,080	142.40	1,008,192	1,008,192
§ 422.124	708 MA organizations	708	1.5	1,062	90.36	95,962	95,962
§ 422.124(g)	708 MA organizations	708	0.5	354	90.36	31,987	31,987
TOTAL	708 MA organizations	5,282	varies	46,291	varies	6,025,071	1,608,453

C. Summary of Proposed Information Collection Requirements and Associated Burden

TABLE III.11: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN

Regulatory Section in Title 42 of the CFR	Brief Description	OMB Control No. (CMS ID No.)	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Cost 1 st Year (\$)	Total Cost Subsequent Years (\$)
§ 422.2	Provider Directory Verification, Updating, and Disclosure	0938-IBD (CMS-10981)	708 MA organizations	708	1.5	1,062	90.36	95,962	95,962
§ 422.123(b)(4)	Provider Directory Verification, Updating, and Disclosure	0938-TBD (CMS-10981)	708 MA organizations	708	3	2,124	90.36	191,925	N/A
§ 422.123(d)(1)-(4) (10 or fewer specified MA plans)	Provider Directory Accuracy Analysis and Accuracy Score	0938-TBD (CMS-10981)	113 MA parent organizations	113	13	1,469	90.36	132,739	132,739
§ 422.123(d)(1)-(4) (11 to 50 specified MA plans)	Provider Directory Accuracy Analysis and Accuracy Score	0938-TBD (CMS-10981)	38 MA parent organizations	38	20	760	90.36	68,674	68,674
§ 422.123(d)(1)-(4) (51 or more specified MA plans)	Provider Directory Accuracy Analysis and Accuracy Score	0938-IBD (CMS-10981)	12 MA parent organizations	12	30	360	90.36	32,530	32,530
§ 422.123(d)(5)	Provider Directory Accuracy Report	0938-IBD (CMS-10981)	113 MA parent organizations	113	8	904	90.36	81,685	81,685
§ 422.123(d)(5)	Provider Directory Accuracy Report	0938-TBD (CMS-10981)	38 MA parent organizations	38	12	456	90.36	41,204	41,204
§ 422.123(d)(5)	Provider Directory Accuracy Report	0938-IBD (CMS-10981)	12 MA parent organizations	12	18	216	90.36	19,518	19,518
§ 422.124(d)	Enrollee Cost Sharing Protections when Provider Directories are Inaccurate	0938-TBD (CMS-10981)	708 MA organizations	708	3	2,124	90.36	191,925	N/A
§ 422.124(e)	Enrollee Cost Sharing Protections when Provider Directories are Inaccurate	0938-TBD (CMS-10981)	708 MA organizations	708	40	28,320	142.40	4,032,768	N/A
§ 422.124(e)	Enrollee Cost Sharing Protections when Provider Directories are Inaccurate	0938-TBD (CMS-10981)	708 MA organizations	708	10	7,080	142.40	1,008,192	1,008,192
§ 422.124	Enrollee Cost Sharing Protections when Provider Directories are Inaccurate	0938-TBD (CMS-10981)	708 MA organizations	708	1.5	1,062	90.36	95,962	95,962
§ 422.124(g)	Enrollee Cost Sharing Protections when Provider Directories are Inaccurate	0938-TBD (CMS-10981)	708 MA organizations	708	0.5	354	90.36	31,987	31,987
Total				5,282	Varies	46,291	Varies	6,025,071	1,608,453

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed

previously, please visit CMS' PRA website at <https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pralisting> or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you comment on these information collection requirements, please submit your comments electronically as specified in the **DATES**

and **ADDRESSES** sections of this proposed rule and identify the rule (CMS-4214-P), the ICR's CFR citation, and the OMB control number.

IV. Regulatory Impact Analysis

A. Statement of Need

This proposed rule addresses several critical needs in the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D)

programs that require regulatory action to ensure program integrity, beneficiary protection, and statutory compliance. Specifically, this rule consists of proposals intended to codify and implement certain statutory requirements of the Consolidated Appropriations Act, 2026 (CAA).

- Proposed changes implementing section 6219 of the CAA (Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals) would reduce the generic drug copayment from for full-benefit dual eligible individuals. This rulemaking would reduce the generic drug copayment from \$1 to \$0 for full-benefit dual eligible individuals at or below 100 percent of the Federal Poverty Level, effective for plan years starting January 1, 2028.

- Proposed changes implementing section 6220 of the CAA (Requiring Enhanced and Accurate Lists of (REAL) Health Providers Act) would establish new provider directory accuracy and accountability requirements for MA organizations beginning in contract year 2028. Without regulatory implementation of these statutory requirements, CMS cannot ensure that MA organizations meet their obligations under Federal law to maintain accurate provider directories, nor can CMS provide the beneficiary cost sharing protections and public transparency mechanisms Congress enacted into law. Specifically, the REAL Health Providers Act requires CMS to establish provider directory verification and updating standards, annual accuracy analyses and scoring, submission of accuracy reports to CMS for public posting, and beneficiary notification and cost sharing protections for enrollees who rely on inaccurate directory information.

- Proposed changes implementing section 6224 of the CAA (Modernizing and Ensuring Pharmacy Benefit Manager Accountability) would

establish new and enhanced requirements governing PBM remuneration, data reporting, pricing transparency, and disclosure of manufacturer agreements within Medicare Part D, along with definitions of key terms and compliance and enforcement mechanisms, including disgorgement of funds to CMS for violations.

The absence of regulatory action would result in statutory non-compliance regarding CAA implementation, ongoing operational inefficiencies, and missed opportunities for program improvement and innovation. Therefore, this rulemaking is necessary to ensure the Medicare program operates effectively, efficiently, and in compliance with Federal law while serving the best interests of Medicare beneficiaries.

B. Overall Impact Analysis

We have examined the impacts of this proposed 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; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; 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 impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President’s priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is significant under section 3(f)(1) of E.O. 12866.

C. Detailed Economic Analysis

Many provisions of this proposed rule have negligible impact either because they are technical provisions or because they are clarifications. Throughout the preamble we have noted when we estimated that provisions have no impact. Additionally, this RIA discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions’ effects are estimated in section III. of this proposed rule, which estimates costs associated with paperwork burden resulting from this rule. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this RIA cross-references impacts from section III. of this proposed rule in order to arrive at the total impact. Table IV.1 summarizes the estimated transfers and costs associated with the various provisions in this proposed rule over a 10-year period. Further details are provided later in this RIA.

TABLE IV.1: SUMMARY OF THE TRANSFERS AND COSTS OF THE PROPOSED RULE BY PROVISION FOR YEARS 2028-2037 (In \$ Millions)

Category of Provisions	Year(s)									
	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037
Transfers										
Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals	99.0	106.0	119.0	130.0	131.0	136.0	143.0	150.0	158.0	165.0
TOTAL TRANSFERS	99.0	106.0	119.0	130.0	131.0	136.0	143.0	150.0	158.0	165.0
From the Medicare Trust Funds to MA Organizations and Part D Sponsors										
COSTS*										
REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026)	6.0	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
TOTAL COSTS	6.0	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6

* Figures in the Costs section of Table IV.1 have been rounded to the nearest tenth of one million. For that reason, numbers in the 2028-2037 column may not equal the sum of columns 2028 through 2037

1. Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals (Section 6219 of the Consolidated Appropriations Act, 2026)

This section provides the impact associated with the proposed provision to eliminate the copayment on non-multi-source generic drugs for the \$1/\$3 low-income subsidy (LIS) beneficiary group. The affected entities include Medicare Part D beneficiaries (specifically full-benefit dual-eligible individuals with incomes at or below 100 percent of the Federal Poverty

Level) and the Medicare program. Impacts are quantified using 2025 Prescription Drug Event (PDE) data. We seek public comment on the assumptions and methodologies described below, particularly where data limitations exist.

The potential benefits of this proposed provision include improved medication access and adherence for low-income Medicare Part D beneficiaries, reduced financial burden for vulnerable populations, and potential long-term health outcome

improvements associated with increased use of clinically appropriate generic medications. To the extent that the proposal induces switching from brand-name drugs to lower-cost generics, this effect is a transfer—a redistribution of drug spending among the Medicare program and beneficiaries, rather than a net benefit or cost of the provision.⁴⁶

Table IV.2 summarizes the estimated benefit, premium, and net Federal cost impacts of the proposed provision over the 2028–2037 period (in millions of dollars).

TABLE IV.2: ESTIMATED BENEFIT, PREMIUM, AND NET FEDERAL COST IMPACTS

CY Incurred	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2028–2037 Total
Benefit Impact (\$M)	\$106	\$113	\$131	\$142	\$144	\$149	\$157	\$165	\$173	\$181	\$1,461
Premium Impact (\$M)	\$6	\$7	\$11	\$12	\$13	\$13	\$14	\$15	\$16	\$16	\$124
Net Federal Cost (\$M)	\$99	\$106	\$119	\$130	\$131	\$136	\$143	\$150	\$158	\$165	\$1,337

The net Federal cost of the proposed provision is estimated at approximately \$1.337 billion over the 2028–2037 period, reflecting the direct copay elimination cost net of premium offsets. The benefit impact of \$1.461 billion reflects the total increase in Medicare program spending attributable to the three modeled effects. The premium impact of \$124 million reflects the partial offset from increased Part D plan premiums resulting from higher program costs.

The elimination of the copayment on non-multi-source generic drugs is a transfer, not a cost of the proposed provision. Beneficiaries in the \$1/\$3 LIS group who previously paid the copay will no longer bear that cost; the Medicare program will absorb it instead. Consistent with OMB Circular A–4's treatment of subsidies as transfer payments, this direct copay elimination effect redirects existing resources from the Medicare program's financing base to the affected beneficiary population; it does not consume real resources.

To the extent that the proposal induces brand-to-generic switching, there may be a partial offsetting transfer

in the form of reduced drug spending—from brand manufacturers to the Medicare program and beneficiaries—as lower-cost generics replace higher-cost brand drugs. This transfer represents a redistribution of drug spending rather than a change in the total resources consumed. This switching effect is assumed to be limited given the relatively modest actual copay differential between brand and generic drugs under the current \$1/\$3 LIS structure.

2. REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026)

The provision implementing the REAL Health Providers Act is expected to increase costs for 708 MA organizations by \$6,025,071 in contract year 2028 and \$1,608,453 annually in subsequent years consistent with the estimates outlined in the Collection of Information section of this proposed rule for provider directory verification, updating and disclosure, the provider directory accuracy analysis and accuracy score, the provider directory accuracy report, and enrollee cost

sharing protections when provider directories are inaccurate. These estimates may change based on public comments and final implementation of requirements including: the final sampling requirements under proposed § 422.123(d)(2), verification methods used for purposes of the accuracy score under proposed § 422.123(d)(3), scoring methodology under proposed § 422.123(d)(4), and annual reporting requirements under proposed § 422.123(d)(5). The burden associated with quarterly hardcopy provider directory addenda under proposed § 422.123(c)(2) and new beneficiary disclosures under proposed § 422.111(b)(12) and (k)(6) may also need to be reconsidered based on public comments and the degree to which they can be incorporated into existing processes.

The provision would also impose burden on the Federal Government. CMS would be responsible for specifying the sampling criteria (§ 422.123(d)(2)), verification methods (§ 422.123(d)(3)), and the weighted accuracy scoring methodology (§ 422.123(d)(4)), as well as receiving

⁴⁶ See OMB Circular A–4 (2003), at https://obama.whitehouse.archives.gov/omb/circulars_a004_a-4/.

and overseeing annual provider directory accuracy reports (§ 422.123(d)(5)). In addition, under proposed § 422.123(e), beginning with contract years beginning on or after January 1, 2029, CMS will post provider directory accuracy scores in a machine-readable file on the CMS website. However, CMS notes that Federal implementation costs associated with this aspect of the provision would be supported by the \$4,000,000 that Congress appropriated to CMS's Program Management Account for fiscal year 2026 to support implementation of the REAL Health Providers Act.

3. Modernizing and Ensuring Pharmacy Benefit Manager Accountability (Section 6224 of the Consolidated Appropriations Act, 2026)

Section 6224 of the CAA requires that, beginning in plan year 2028, remuneration to PBMs and affiliates of PBMs in connection with the utilization of Part D drugs be limited to bona fide service fees reflecting fair market value, as defined by the Secretary, subject to certain exceptions. The Congressional Budget Office has estimated that this provision would reduce federal direct spending by approximately \$444 million over the 2026–2035 period. Contract arrangements between PBMs, Part D plan sponsors, pharmacies, and pharmaceutical manufacturers are complex. The contracts between PBMs and Part D plan sponsors vary widely by the size of the sponsor and vertical integration of some PBM functions has increased in recent years. While it is possible that the fair market value definition proposed in this rule will result in lower service fees, we do not have sufficient data on the difference between the proposed fair market value definition and current fee structures or the range of potential PBM responses to form a reasonable analysis of the overall impact to the Part D program. For PBMs and Part D plan sponsors with common corporate ownership, any changes to the PBM fee structure may be offset by changes to the Part D bid to achieve the same overall target revenue of the parent organization. For PBMs without such a related party arrangement, they may adjust other terms of their agreements with Part D plan sponsors or pharmacies to the extent allowable under current laws and regulations. Alternatively, PBMs could balance lower fees under Medicare with higher fees on other lines of business. Without a more comprehensive understanding of how the fair market value definition relates to current contracting levels and what flexibility the PBMs will have to adjust other contract terms, the impact of this

proposed rule is uncertain. We welcome comments regarding the quantification of the impact of these provisions.

D. Alternatives Considered for REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026)

In this section, we include discussions of alternatives considered for the provisions to which they are applicable. CMS did not develop an alternatives considered section for several of the provisions in this proposed rule as they generally are direct implementations of Federal laws or codifications of existing policy for MA and Part D.

1. Alternatives Considered for Provider Directory Verification Requirements (§ 422.123(b))

Under proposed § 422.123(b), MA organizations would verify provider directory information using CMS-specified verification methods. CMS considered limiting which verification methods could be used for particular provider directory elements during the routine 90-day and 12-month verification cycles but did not propose these limitations because they could increase administrative burden. CMS proposes limitations for verification conducted for purposes of calculating the accuracy score and may revisit these approaches as provider data sources and the NPD develop. The proposed 12-month verification cycle for specified hospitals and facilities is intended to limit verification burden on both MA organizations and providers. CMS also recognizes that MA organizations may need to use more than one verification method to verify all required provider directory elements, and that direct provider verification may increase burden depending on the method and frequency of contact.

2. Alternatives Considered for Provider Directory Accuracy Analysis and Sampling Methodology (§ 422.123(d)(1) and (2))

Consistent with section 1857(e)(6)(A) of the Act, proposed § 422.123(d)(1) and (2) would require an annual plan-level accuracy analysis using a random sample of providers. CMS considered alternative approaches for identifying high-inaccuracy provider specialty types, geographic stratification, sample size parameters, consolidation of overlapping provider samples, and timing of sample selection. In evaluating these approaches, CMS considered data availability, administrative burden, operational flexibility, comparability across plans, duplicative verification,

and potential for gaming. CMS seeks comments on several of these considerations before finalizing the sampling requirements. In particular, CMS recognizes that larger samples could increase burden on MA organizations and providers and intends to consolidate overlapping plan-level samples across an MA organization to reduce duplicative provider contacts. CMS is also considering minimum and maximum sample parameters that balance meaningful accuracy results with administrative burden.

3. Alternatives Considered for Provider Directory Accuracy Score and Scoring Methodology (§ 422.123(d)(3) and (4))

Consistent with section 1857(e)(6)(B) of the Act, proposed § 422.123(d)(3) and (4) would establish verification and weighted scoring requirements for calculating provider directory accuracy scores. CMS considered incorporating results from the routine 90-day and 12-month verification cycles into the accuracy score, alternative approaches for weighting those results relative to the annual sample, and giving greater weight to high-inaccuracy specialty types. CMS did not propose these approaches because they could increase the complexity and burden of the scoring methodology but seeks comments on whether they should be considered. CMS did not propose more complex scoring alternatives that could increase burden on MA organizations and providers.

4. Alternatives Considered for Provider Directory Accuracy Reporting (§ 422.123(d)(5))

Consistent with section 1857(e)(6)(A)(ii) of the Act, proposed § 422.123(d)(5) would require MA organizations to submit an annual provider directory accuracy report to CMS. CMS considered requiring additional reporting elements, including specialty-level response and sampling data and administrative cost information, and whether the accuracy analysis and score should be independently reviewed and certified by a qualified third party. CMS also seeks comments on whether the proposed reporting deadline provides sufficient time for MA organizations to complete the report. Requiring additional reporting elements or independent third-party review and certification could increase reporting and compliance burden beyond the proposed annual report. CMS seeks comments on these considerations, including administrative costs to MA organizations and contracted providers.

5. Alternatives Considered for Exception for Specified MA Plans With Low Enrollment

Section 1857(e)(6)(C) of the Act permits the Secretary to waive the annual accuracy analysis and reporting requirements for specified MA plans with low enrollment. CMS considered using existing MA minimum enrollment thresholds or the Star Ratings threshold to define low enrollment. Although an exemption could reduce burden on smaller plans, CMS is inclined to apply the requirements to all specified MA plans and seeks comments on whether and how to implement the exception. If implemented, a low-enrollment exception would reduce the accuracy analysis and reporting burden for qualifying plans. However, those plans would remain subject to the verification and updating requirements under proposed § 422.123(b) and (c).

6. Alternatives Considered for Provider Directory Public Transparency (§ 422.123(e))

Consistent with section 1857(e)(6)(D) of the Act, proposed § 422.123(e) would require CMS to post provider directory accuracy scores in a machine-readable file beginning in contract year 2029. CMS is also considering making the scores available through CMS APIs and posting them on MPF. The required machine-readable posting would impose Federal implementation burden on CMS. Making scores available through additional CMS APIs or MPF would require additional Federal implementation beyond the statutory machine-readable posting.

7. Alternatives Considered for Enrollee Cost Sharing Protections (§ 422.124)

Consistent with section 1852(d)(7) of the Act, proposed § 422.124 would establish cost sharing protections for enrollees who rely on inaccurate provider directory information. CMS is considering whether the protections should also apply to reliance on hardcopy directories, whether MA organizations should publicly post daily provider directories rather than provide archived information to CMS upon

request, and whether to establish specific formatting requirements for archived provider directory data. CMS seeks comments on these alternatives and the proposed data-retention period. The alternatives could affect burden on MA organizations by changing the information and systems needed to document enrollee reliance on provider directory information. Publicly posting daily directories or establishing specific archive formats could increase system and maintenance burden relative to the proposed approach, while extending the protections to hardcopy directories could require additional verification of the directory information relied upon.

8. Alternatives Considered for Provider Directory Disclosure Requirements (§ 422.111(b)(12) and (k)(6))

Consistent with sections 1852(d)(7)(B) and 1851 (d)(4)(F) of the Act, proposed § 422.111(b)(12) and (k)(6) would establish disclosures concerning provider directory accuracy scores and enrollee cost sharing protections. In addition to the required provider directory and EOB disclosures, CMS is considering including notice of the cost sharing protections in the SB and EOC to provide information before and after enrollment. Including the cost sharing protection notice in the SB and EOC would increase the number of beneficiary materials MA organizations would need to update and distribute and could result in additional administrative burden beyond the proposed provider directory and EOB disclosures.

E. Regulatory Review Cost Estimation

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret the proposed rule, then we should estimate the cost associated with regulatory review. We have received approximately 20,000 comments specific to the provisions of our recent proposed rule, and we estimate that a similar number will review this rule upon publication in the **Federal Register**.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this proposed rule is \$135.54 per hour, including fringe benefits, overhead, and other indirect costs (http://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it will take approximately 1 hour for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore \$135.54 (1 hour × \$135.54). Therefore, we estimated that the maximum total cost of reviewing the proposed rule is \$2.7 million (\$135.54 × 20,000 reviewers). However, we expected that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but review just the sections that are relevant to them. We expect that on average (with fluctuations) 10 percent of the proposed rule will be reviewed by an individual reviewer; we, therefore, estimate the total cost of reviewing to be \$271,080. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We noted that this analysis assumes one reader per contract. Some alternatives included assuming one reader per parent organization. Using parent organizations instead of contracts would reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The rationale for this is that a parent organization might have local reviewers assessing potential region-specific effects from the rule.

F. Accounting Statement and Table

Table IV.3 summarizes costs, savings, and transfers by provision. As required by OMB Circular A–4 (available at <https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf>), we have prepared an accounting statement in Table IV.3 showing the transfers and costs associated with the provisions of this rule over a 10-year period or for contract years 2028 through 2037.

TABLE IV.3: ACCOUNTING STATEMENT - CLASSIFICATIONS OF ESTIMATED TRANSFERS AND COSTS, CONTRACT YEARS 2028-2037 (MILLIONS)

Category	3% Discount Rate	7% Discount Rate
<i>COSTS</i>		
Annualized monetized costs to MA Organization and PD Sponsors	2.1	2.2
<i>TRANSFERS</i>		
Annualized monetized transfers	128.14	121.3
From Federal Government to MA Organizations and PD Sponsors		

G. Impact on Small Businesses—Regulatory Flexibility Act (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

We believe this proposed rule will have a direct economic impact on beneficiaries and health insurance plans. Based on the size standards set by the Small Business Administration (SBA) effective March 17, 2023, (for details, see the Small Business Administration's website at <https://www.sba.gov/document/support-table-size-standards>), Direct Health and Medical Insurance Carriers, classified using the NAICS code 524114, have a \$47 million threshold for "small size." Many Medicare Advantage organizations (about 30 to 40 percent) are not-for-profit,⁴⁷ which allows them to qualify as "small entities" so long as they are independently owned and operated and nondominant in their field. We believe all of the not-for-profit organizations qualify as small under the aforementioned criteria. Of the 1,071 businesses using this NAICS code, we believe 799 (or 74.6 percent) are small businesses.

Using CMS's own payment records, we have been able to make estimates as to the minimum size of the smallest Medicare Advantage and Part D insurance contracts. The vast majority of Part D contracts and MA organizations must meet minimum size and financial thresholds that ensures their resilience. Based on payments made for the current year, we estimated that the three smallest MA parent organizations, excluding new entities that are not yet required to fulfill CMS enrollment thresholds, are expected to average over

\$5 million in total receipts by the end of 2026.

The RFA does not define the terms "significant economic impact" or "substantial number." The SBA advises that this absence of statutory specificity allows what is "significant" or "substantial" to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a "significant economic impact" to be 3 to 5 percent or more of the affected entity's costs or revenues, and a "substantial number" to mean 5 percent or more of affected small entities within a given industry.⁴⁸

1. Operational Aspects of the Medicare Program

To explain our position, we will first note certain operational aspects of the Medicare program. Each year, MA organizations submit a bid for each plan for furnishing Parts A and B benefits and the entire bid amount is paid to the plan by the government through the Medicare Trust Funds, if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that, historically, only 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees). Part D sponsors also submit a bid for each plan, and the payments made to stand-alone Part D plans (PDPs) are covered by the Supplementary Medical Insurance Medicare Trust Fund.

MA plans can also offer enhanced benefits—that is, benefits not covered under Original Medicare. These enhanced benefits are paid for through enrollee premiums, rebates or a combination. Under the statutory payment formula, if the plan bid submitted by an MA organization for

furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is, benefits not covered under Original Medicare) and/or to lower beneficiary cost sharing, Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

Part D sponsors submit bids and plans are paid through a combination of Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries, Part D plans receive special government payments to cover most of premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by these insurers is funded by the government and, in some cases, by enrollee premiums. As a result, MA plans, Part D plans, Prescription Drug Plans, and PACE organizations are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

In addition to the direct costs discussed earlier, there are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of MA plans (including MA-PD plans) bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government, given that as previously noted, under the statutory payment formula, if a bid submitted by a MA plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a beneficiary rebate, which must be used to provide supplemental benefits or lower beneficiary cost sharing or both, Part B or Part D premiums. If the plan's

⁴⁷ Medicare Advantage/Part D Contract and Enrollment Data, <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data>.

⁴⁸ U.S. Department of Health and Human Services, Guidance on Proper Consideration of Small Entities in Rulemaking, <https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf>.

bid exceeds the administratively set benchmark, the beneficiary pays the difference in the form of a basic premium. However, as also noted previously, the number of MA plans bidding above the benchmark to whom this burden applies does not meet the RFA criteria of a significant number of firms.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This analysis must conform to the provisions of section 603 of the RFA. Therefore, the Secretary has certified that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

If the provisions of the rule were to cause bids to increase and if the benchmark remains unchanged or increases by less than the bid does, the result could be a reduced rebate. Plans have different ways to address this in the short-term, such as reducing administrative costs, modifying benefit structures, or adjusting profit margins. These decisions may be driven by market forces. Part of the challenge in pinpointing the indirect effects is that there are many other factors combining with the effects of the rule, making it effectively impossible to determine whether a particular policy had a long-term effect on bids, administrative costs, margins, or supplemental benefits.

2. Anticipated Costs and Savings

As indicated in Table IV.1, the proposals described in this rule are expected to result in de minimis costs amounting to approximately \$6 million in 2028, with costs of approximately \$1.6 million expected in subsequent years. MA organizations and Part D sponsors will be the entities most economically impacted by this rule.

The costs incurred by MA and Part D contracts fall below the HHS significance threshold. For an MA organization that incurred all anticipated costs stemming from the REAL Health Providers Act provisions of this rule, they may be expected to see \$17,105 in new costs in 2028 and \$10,867 a year thereafter. Measured against the average revenue of the smallest MA parent organizations as identified earlier in this section (\$5 million), these new costs resulting from the REAL Health Providers Act

provision are expected to reflect less than 3 percent of the affected entity's costs or revenues.

In summation, this proposed rule will not have a significant economic impact on a substantial number of small entities. The vast majority of MA organizations and Part D sponsors are expected to see de minimis costs as a result of this rule.

H. 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 proposed rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of \$193 million or more.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

J. E.O. 14192, “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”. We estimate that this rule generates \$1.4 million in annualized costs at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

K. Conclusion

This proposed rule, if finalized, will result in net annualized costs ranging between \$2.1 and \$2.2 million for calendar years 2028 to 2037, at the 3 percent and 7 percent discount rates, respectively. The costs are attributable to the provision REAL Health Providers Act (Section 6220 of the Consolidated Appropriations Act, 2026). This proposed rule will also result in net annualized monetized transfers ranging

between \$121.3 million and \$128.14 million for calendar years 2028 to 2037, at the 3 percent and 7 percent discount rates respectively. These transfers result from the provision Adjustments to Medicare Part D Cost-Sharing Reductions for Low-Income Individuals.

XII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 14, 2026.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

- 1. The authority for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

- 2. Section 422.2 is amended by adding definitions for “Maximum fair price (MFP)”, “Provider directory,” “Provider directory accuracy score,” “Provider directory information,” “Selected drug”, “and “Specified MA plan” in alphabetical order.

The additions read as follows:

§ 422.2 Definitions

* * * * *

Provider directory means, for specified MA plans, as defined in this section, the publicly available listing, maintained and distributed by an MA organization in accordance with § 422.2267(e)(11), of providers that are

currently contracted and participating in that MA plan's provider network, and containing the information under § 422.111(b)(3)(i)(A), (b)(3)(i)(B), and (b)(12).

Provider directory accuracy score means the score reflecting the accuracy of provider directory information calculated and reported in accordance with § 422.123(d).

Provider directory information means information enrollees may need to access covered benefits from a provider with which an MA organization offering a specified MA plan has an agreement for furnishing items and services covered under such plan, including, at a minimum, all of the following:

- (1) Provider name.
- (2) Specialty.
- (3) Contact information, including telephone number(s).
- (4) Primary office or facility address(es) where covered items or services are furnished.
- (5) Whether the provider is accepting new patients.
- (6) Accommodations for people with disabilities.
- (7) Cultural and linguistic capabilities
- (8) Telehealth capabilities.
- (9) Common ownership or control disclosure. For purposes of disclosing common ownership or control as part of the provider directory information described in this section, an MA organization must identify any network provider, provider group, facility, or supplier that is owned or controlled, in whole or in part, directly or indirectly, by the MA organization, by the MA organization's parent organization, by a subsidiary or affiliate of the MA organization, or by any entity that is under common ownership or control with the MA organization.

Specified MA plan means either of the following:

- (1) A network-based plan as defined in this section.
- (2) An MA private fee-for-service plan that meets the access standards under § 422.114, in whole or in part, through entering into contracts or agreements with a network of providers.

- 3. Section 422.111 is amended by—
- a. Revising paragraph (b)(3)(i);
 - b. Adding paragraph (b)(12);
 - c. Revising paragraphs (h)(2) and (k) paragraph heading; and
 - d. Adding paragraph (k)(6).

The revisions and additions read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(3) * * *

(i)(A) The number, mix, and distribution of providers from whom enrollees may reasonably be expected to obtain covered benefits;

(B) Provider directory information as defined in § 422.2 and in accordance with § 422.2267(e)(11);

(C) Any out-of-network coverage;

(D) Any point-of-service option, including the supplemental premium for that option; and

(E) How the MA organization meets the requirements of §§ 422.112 and 422.114 for access to services offered under the plan.

* * * * *

(12) *Cost sharing protections and accuracy score in provider directory.* Each MA organization offering a specified MA plan must disclose, in a form and manner specified by CMS, information within the provider directory regarding cost sharing protections and accuracy, including—

(i) For contract year 2028 and subsequent contract years—by no later than the first day of the annual coordinated election period under § 422.62(a)(2)—a plain-language description of the enrollee cost sharing protections required under § 422.124; and

(ii) For contract year 2029 and subsequent contract years, the most recent provider directory accuracy score reported to the Secretary in accordance with § 422.123(d)(5), prominently displayed.

* * * * *

(h) * * *

(2) A publicly available internet website that complies with the website requirements in §§ 422.2265 and 422.120(a). Posting copies of required materials on the website does not relieve the MA organization of its responsibility to provide hard copies to enrollees upon request in accordance with § 422.2267(d) or when required by CMS.

* * * * *

(k) *Explanation of benefits.* * * *

(6) *Provider directory cost sharing protections.* For contract year 2028 and subsequent contract years, for each specified MA plan, the MA organization must include, in at least the first explanation of benefits issued to an enrollee in a plan year, a plain-language description of all of the following:

(i) The cost sharing protections under § 422.124.

(ii) The process by which the enrollee or the enrollee's representative may request application of the protections under § 422.124, including, but not

limited to, a toll-free telephone number and website URL through which such requests may be submitted.

(iii) The process by which the enrollee or the enrollee's representative may request a correction if cost sharing was applied in a manner inconsistent with § 422.124.

* * * * *

■ 4. Section 422.120 is amended by revising paragraph (b)(1) to read as follows:

§ 422.120 Access to published provider directory information.

* * * * *

(b) * * *

(1) The MA plan's network of contracted providers, including the provider directory information as defined in § 422.2, verified and updated in accordance with § 422.123(b) and (c); and

* * * * *

■ 5. Subpart C is amended by adding § 422.123 to read as follows:

§ 422.123 Provider directory accuracy.

(a) *Applicability.* This section applies to each MA organization offering a specified MA plan, as defined in § 422.2, for contract year 2028 and subsequent contract years.

(b) *Verification.*

(1) *Verification frequency.*

(i) Except as provided in paragraph (b)(1)(ii) of this section, the MA organization must verify the provider directory information of each provider listed in that specified MA plan's provider directory in accordance with paragraph (b)(2) of this section not less frequently than once every 90 days and update the provider directory in accordance with paragraph (c) of this section, if applicable.

(ii) The MA organization must verify the provider directory information of hospitals and other facilities as listed in § 422.116(b)(2)(i), (iv), and (v) in accordance with paragraph (b)(2) of this section not less frequently than once every 12 months and update the provider directory in accordance with paragraph (c) of this section, if applicable.

(2) *Verification methods.* The MA organization must use one or more of the following CMS-specified provider directory verification methods to meet the requirements in paragraph (b)(1) of this section:

(i) Internal plan information.

(ii) Telephonic verification.

(iii) Email verification.

(iv) Provider attestations.

(v) Claims data.

(vi) Data sources maintained by CMS.

(vii) Other verification methods specified by CMS.

(3) *Unable-to-verify flag.* If the MA organization is unable to verify provider directory information with respect to a provider during the applicable verification cycle specified in paragraph (b)(1) of this section, then the MA organization must include in the provider directory a clear indication that the information of such provider may not be up to date. This update must be completed in accordance with paragraph (c)(1) of this section.

(4) *Provider contract term required.* The MA organization must include a term in each provider contract for a specified MA plan obligating the provider to maintain current and accurate provider directory information as defined in § 422.2.

(c) *Updating.* (1) Except as provided in paragraph (c)(4) of this section, the MA organization must update both the online and PDF or otherwise printable electronic copy of the provider directory (as specified in § 422.2265(b)(3)) within at least 30 days of receiving information requiring update.

(2) The MA organization must send a quarterly addendum containing updates to all enrollees who have requested a physical hardcopy provider directory.

(3) The MA organization must include a disclaimer on the physical hardcopy provider directory that recommends beneficiaries check the online provider directory or contact the MA organization for the latest updates.

(4) *Removal of non-contracted providers.* The MA organization must remove a provider from the provider directory no later than 5 business days after the date on which the MA organization determines that the provider is no longer participating in the network of the specified MA plan.

(d) *Accuracy analysis and accuracy score—(1) Annual accuracy analysis.* Beginning with contract years beginning on or after January 1, 2028, each MA organization must conduct an annual analysis estimating the accuracy of all provider directory information, except for “provider name,” “cultural and linguistic capabilities,” and “common ownership or control disclosure,” of each specified MA plan.

(2) *Sampling frame and methodology.* The analysis specified in paragraph

(d)(1) of this section must use a random sample of provider records sampling methodology, as specified by CMS.

(i) When determining the provider specialty types with high provider directory inaccuracy rates, CMS—

(A) Will consider all provider specialty types included in the Medicare specialty codes and National Uniform Claim Committee taxonomy, and

(B) May consider other provider specialty types and providers furnishing supplemental benefits.

(ii) CMS has identified the following as provider specialty types with high provider directory inaccuracy rates:

(A) Mental health or substance use disorder treatment provider specialty types specified by CMS.

(B) [RESERVED]

(iii) The MA organization must identify the sampling frame as provider records in the provider directory with a unique provider, address, and phone number.

(iv) The MA organization must identify the sample using the following methodology:

(A) Sixty-five percent of the sample set consists of providers in the directory, excluding those with the provider specialty types identified in paragraph (d)(2)(ii) of this section; and

(B) Thirty-five percent of the sample set consists of providers in the directory with the provider specialty types identified in paragraph (d)(2)(ii) of this section.

(3) *Accuracy score required.* The MA organization must estimate an accuracy score reflecting the accuracy of the provider directory information. The accuracy score must be all of the following:

(i) Estimated using the verification methods specified in paragraph (b)(2) of this section, for the specified provider directory elements, as follows:

(A) Internal plan information may be used for confirmation of network participation status and specialty.

(B) Telephonic verification may be used for confirmation of all of the following:

(1) Specialty.

(2) Contact information.

(3) Primary office or facility address(es).

(4) Whether the provider is accepting new patients.

(5) Accommodations for people with disabilities.

(6) Telehealth capabilities.

(C) Email verification may be used for confirmation of all of the following:

(1) Specialty.

(2) Contact information.

(3) Primary office or facility address(es).

(4) Whether the provider is accepting new patients.

(5) Accommodations for people with disabilities.

(6) Telehealth capabilities.

(D) Provider attestations may be used for confirmation of all of the following:

(1) Network participation status.

(2) Specialty.

(3) Contact information.

(4) Primary office or facility address(es).

(5) Whether the provider is accepting new patients.

(6) Accommodations for people with disabilities.

(7) Telehealth capabilities.

(E) Claims data may be used for confirmation of all of the following:

(1) Network participation status.

(2) Specialty.

(ii) Based on the verification results for the random sample specified in paragraph (d)(2)(i) and (d)(2)(ii) of this section using the sampling methodology specified in paragraph (d)(2)(iii) of this section.

(iii) Represented in the form of a letter grade, as specified in paragraph (d)(4)(vi) of this section.

(4) *Scoring methodology.* The MA organization must calculate the Provider Directory Accuracy Score in accordance with the specified weighted scoring methodology, as follows:

(i) Sum the number of accurate records for each element across all providers in the sample.

(ii) Divide the number of accurate records for each element by the number of providers in the sample to determine the Accuracy Percentage per Element.

(iii) Multiply the Accuracy Percentage per Element by the Element Weight, as defined in Table 1, to determine the Weighted Score per Element.

TABLE 1 TO PARAGRAPH (d)(4)(iii)

Element	Element weight (%)
Network participation status	40
Specialty	10
Contact information, including telephone number(s)	20
Primary office or facility address(es) where covered items or services are furnished	20

TABLE 1 TO PARAGRAPH (d)(4)(iii)—Continued

Element	Element weight (%)
Whether the provider is accepting new patients	3
Accommodations for people with disabilities	3.5
Telehealth capabilities	3.5

(iv) Sum the Weighted Score per Element, to determine the Final Composite Score.

(v) Multiply the Final Composite Score by 100 to convert to a percentage, then round to the nearest whole number to determine the Rounded Composite Score.

(vi) To determine the final Provider Directory Accuracy Score, convert the Rounded Composite Score to the appropriate letter grade, as follows:

(A) 90 to 100 percent is equivalent to a grade of “A”.

(B) 80 to 89 percent is equivalent to a grade of “B”.

(C) 70 to 79 percent is equivalent to a grade of “C”.

(D) 60 to 69 percent is equivalent to a grade of “D”.

(E) 50 to 59 percent is equivalent to a grade of “E”.

(F) 49 percent and below is equivalent to a grade of “F”.

(5) *Reporting to CMS.* (i) The MA organization must submit to CMS an annual provider directory accuracy report containing the results of the accuracy analysis specified in paragraph (d)(1) of this section, including the provider directory accuracy score for each specified MA plan.

(ii) The report must be submitted not later than the first Monday in April of the year following the contract year being measured, in a form and manner specified by CMS.

(e) *Public transparency.* Beginning with contract years beginning on or after January 1, 2029, CMS will post provider directory accuracy scores as reported under paragraph (d)(5) of this section in a machine-readable file on the CMS website.

■ 6. Subpart C is amended by adding § 422.124 to read as follows:

§ 422.124 Cost sharing protections for reliance on incorrect provider directory information.

(a) *Applicability.* This section applies to a specified MA plan as defined in § 422.2 for contract year 2028 and subsequent contract years.

(b) *General rule.* If an enrollee in a specified MA plan is furnished an item or service by a provider that is not participating in the plan’s network but is listed in the plan’s online provider

directory as defined in § 422.2 on the date on which the appointment is made, and if such item or service would otherwise be covered under the plan if furnished by a provider that is participating in the plan network, the MA organization offering the plan must ensure the enrollee is only responsible for the lesser of—

(1) The amount of cost sharing that would apply if the provider had been participating in the plan network; or

(2) The amount of cost sharing that would otherwise apply.

(c) *Access to cost sharing protections.* The MA organization must apply the protections under paragraph (b) of this section without requiring that an enrollee makes a request when the MA organization knows or reasonably should know that the protections apply.

(1) An enrollee or the enrollee’s authorized representative may also submit a request verbally or in writing to their MA organization.

(2) The enrollee request for the cost sharing protections must be treated by the MA organization as an organization determination or reconsideration request, as applicable, consistent with subpart M of this part.

(d) *Documentation for date appointment was made.* Beginning January 1, 2028, consistent with § 422.202(f), MA organizations must include a term in each provider contract for a specified MA plan obligating the provider to supply documentation of the earliest date on which the enrollee’s appointment was made, regardless of any subsequent rescheduling.

(1) Acceptable documentation includes—

(i) A paper or electronic record from the provider’s scheduling system; or

(ii) A written or electronic confirmation sent to the enrollee or their authorized representative by the provider.

(2) If the documentation described in paragraph (d)(1) of this section is not reasonably obtainable, a signed attestation from the provider accompanied by any available corroborating information, including but not limited to a calendar entry, a referral record, electronic communications, or a phone log, is sufficient to establish the

date on which the appointment was made. The contract term required under this paragraph must survive the expiration or termination of the contract between the MA organization and the provider for not less than 10 years beginning on the date the contract expiration or termination becomes effective.

(e) *Provider directory archiving and verification.* The MA organization must verify whether the provider was listed as an in-network provider in the specified MA plan’s online provider directory on the date the enrollee’s appointment was made, by referencing archived electronic provider directory data maintained online by the MA organization. Archived provider directory data maintained under this paragraph must be—

(1) Sufficient to identify whether any provider was listed in the plan’s online directory at any point on a given date;

(2) Retained for not less than 10 years, consistent with the record retention requirements at § 422.504(d); and

(3) Made available to CMS upon request within 5 business days.

(f) *Absence of documentation.* If the MA organization cannot obtain documentation demonstrating the date on which the appointment was made or cannot verify online provider directory data within the applicable standard or expedited organization determination timeframes under subpart M of this part, the provider directory cost sharing protections must be applied in favor of the enrollee. This default application may be reversed if the MA organization is able to clearly demonstrate that the cost sharing protections do not apply.

(g) *Application of cost sharing protections.* (1) If the MA organization collects cost sharing from an enrollee in excess of the amount permitted under the protections, the MA organization must refund the excess amount to the enrollee consistent with § 422.270(b).

(2) The MA organization must treat cost sharing applied under paragraph (b) of this section as in-network cost sharing for purposes of the maximum out-of-pocket limit consistent with § 422.100(f)(4).

■ 7. Section 422.202 is amended by adding paragraphs (e) and (f) to read as follows:

§ 422.202 Participation procedures.

* * * * *

(e) [Reserved]

(f) *Cost sharing protections for enrollee reliance on incorrect provider directory information.* Beginning January 1, 2028, an MA organization that operates a specified MA plan as defined in § 422.2 must include a term in each contract obligating the provider to supply documentation of the earliest date on which the enrollee's appointment was made consistent with the requirements at § 422.124(d).

■ 8. Section 422.504 is amended by adding paragraph (a)(22) to read as follows:

§ 422.504 Contract provisions.

(a) * * *

(22) To comply with the provider directory accuracy requirements under § 422.123(d)—for contract year 2028 and subsequent contract years—for each specified MA plan.

* * * * *

■ 9. Section 422.2265 is amended by—
■ a. Revising paragraph (b)(3); and
■ b. Adding paragraph (b)(15).

The revision and addition read as follows:

§ 422.2265 Websites.

* * * * *

(b) * * *

(3) An accurate provider directory for each specified MA plan that includes provider directory information for each provider that is currently contracted and participating in the plan's provider network, and a PDF or otherwise printable electronic copy of the provider directory.

* * * * *

(15) A description of the quality improvement program required under §§ 422.152 and 422.111(b)(9).

* * * * *

■ 10. Section 422.2267 is amended by revising paragraphs (e)(11) introductory text and (e)(11)(iv); to read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(11) *Provider Directory.* This is a model communications material through which plans must provide the information under § 422.111(b)(3)(i) and (12). The Provider Directory must do all of the following:

* * * * *

(iv) Be verified and updated in accordance with § 422.123(b) and (c)

(for contract year 2028 and subsequent contract years).

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 11. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 12. Section 423.505 is amended by adding paragraph (b)(28) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(28) Provide that contracts between the Part D plan sponsor and any pharmacy benefit manager, as defined in subpart BB of this part, comply with the requirements of subpart BB of this part, as applicable.

* * * * *

■ 13. Section 423.782 is amended by revising paragraph (a)(2)(iii) to read as follows:

§ 423.782 Cost-sharing subsidy.

* * * * *

(a) * * *

(2) * * *

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of the following:
(A) For plan years prior to January 1, 2028, a copayment amount of not more than \$1 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or \$3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(B) For plan years beginning on or after January 1, 2028, a copayment of \$0 for a generic drug or biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, and not more than \$1 for a preferred multiple source drug (as defined under section 1927(k)(7)(A)(i) of the Act) or \$3 for any other covered drug, with such amounts adjusted annually by the percentage increase in the Consumer Price Index as of September of the previous year,

rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(C) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

* * * * *

■ 14. Part 423 is amended by adding subpart BB to read as follows:

Subpart BB—Modernizing and Ensuring Pharmacy Benefit Manager Accountability

Sec.

423.2800 Basis and scope.

423.2802 Definitions.

423.2804 Pharmacy benefit manager status.

423.2806 Affiliate status.

423.2808 Part D plan sponsor contracts

423.2810 Pharmacy benefit manager and affiliate remuneration

423.2812 Transparency regarding guarantees and cost performance evaluations.

423.2814 Annual pharmacy benefit manager reporting requirements.

423.2816 Written explanation of contracts or agreements with manufacturers.

423.2818 Audit rights.

423.2820 Compliance and enforcement.

423.2822 Confidentiality and restriction on use of information.

Subpart BB—Modernizing and Ensuring Pharmacy Benefit Manager Accountability

§ 423.2800 Basis and scope.

(a) *Basis.* This subpart implements subsection 1860D–12(h) of the Act.

(b) *Scope.* This subpart sets forth the requirements of section 6224 of the Consolidated Appropriations Act, 2026, which establishes requirements for prescription drug plans and pharmacy benefit managers in relation to services in connection with the utilization of Part D drugs.

§ 423.2802 Definitions.

As used in this subpart, the following definitions apply:

Affiliate means, with respect to a pharmacy benefit manager or Part D plan sponsor, any entity that satisfies the ownership or control standard at § 423.2806(a) or the functional relationship standard at § 423.2806(b).

Bona fide service fee means any payment that meets the requirements of § 423.2810(b).

Fair market value has the meaning described at § 423.2810(e).

Fully passed through means that the Part D plan sponsor receives 100 percent of the gross economic value of each manufacturer rebate, discount, or other price concession attributable to Part D drug utilization. A pharmacy benefit manager or affiliate of such pharmacy benefit manager may not reduce, offset, net, hold back, retain, reclassify, or otherwise diminish the

value passed through to the Part D plan sponsor, including through administrative fees, data fees, aggregation fees, reconciliation charges, or other deductions.

Incentive payment means any payment that meets the requirements of § 423.2810(c).

Intermediary means any person or entity in a chain of contractual or delegated relationships, of any length, through which one or more PBM functions are performed on behalf of a Part D plan sponsor or prescription drug plan.

Pharmacy benefit manager (PBM) means any person or entity that satisfies the general rule in § 423.2804(a).

PBM function means acting as a price negotiator or group purchaser or managing the prescription drug benefits provided by a Part D plan sponsor or plan, when performed by any person or entity, directly or through an intermediary, on behalf of a Part D plan sponsor or prescription drug plan, including any of the following activities:

- (1) Processing and payment of claims for prescription drugs.
- (2) Drug utilization review.
- (3) Processing of drug prior authorization requests.
- (4) Adjudication of appeals or grievances related to the prescription drug benefit.
- (5) Contracting with network pharmacies.
- (6) Controlling the cost of Part D drugs.
- (7) Providing related services.

Related service means an activity, service, or function that is performed on behalf of a Part D plan sponsor or prescription drug plan and has a direct nexus to the activities described in paragraphs (1) through (6) of the definition of PBM function. An activity, service, or function has a direct nexus to the activities described at (1) through (6) of the definition of PBM function if it is one of the following:

- (1) Integral to such activity.
- (2) Necessary to carry out such activity.
- (3) Performed in support of such activity.

Remuneration means anything of value, whether provided directly or indirectly, overtly or covertly, in cash or in kind, including but not limited to any of the following:

- (1) Monetary payments.
- (2) Non-cash consideration.
- (3) Administrative fees, data fees, and service fees.
- (4) Spread pricing and retained margins.
- (5) Rebates, discounts, and chargebacks.

(6) Price concessions, credits, and offsets.

(7) Up-front payments and coupons.

(8) Free or reduced-price goods or services, and goods in kind.

(9) Grants and in-kind benefits.

(10) Guarantee reconciliation amounts.

(11) Interest payments and financing benefits.

(12) Any other direct or indirect financial advantage.

§ 423.2804 Pharmacy benefit manager status.

(a) *General rule.* A person or entity qualifies as a pharmacy benefit manager, regardless of how it describes itself, if it satisfies both of the following conditions:

(1) The person or entity has a written contract with a Part D plan sponsor, either directly or through a parent organization of such Part D plan sponsor.

(2) The person or entity, directly or through an intermediary, performs at least one PBM function, as defined at § 423.2802 on behalf of the Part D plan sponsor or prescription drug plan with which it has such written contract.

(b) *Performance standard.* A person or entity satisfies the performance element of paragraph (a)(2) and (c)(2) of this section upon performing one or more PBM functions on any occasion during a calendar year, regardless of the frequency, volume, regularity, or materiality of such performance.

(c) *Performance through an intermediary.* Any person or entity that causes, arranges, procures, or relies on an intermediary to perform a PBM function is deemed to have performed that function for purposes of this subpart. A person or entity qualifies as a pharmacy benefit manager acting through an intermediary if—

(1) The person or entity holds a written contract with the Part D plan sponsor, either directly or through a parent organization of such Part D plan sponsor, to provide or arrange PBM functions;

(2) The person or entity causes, arranges, procures, or relies on an intermediary to perform one or more PBM functions on behalf of the Part D plan sponsor or prescription drug plan as described in such written contract; and

(3) That intermediary performs such function on behalf of such Part D plan sponsor or prescription drug plan.

(d) *Performance by Part D plan sponsors.*

A Part D plan sponsor does not meet the performance standard in paragraph (a)(2) of this section based solely on the

sponsor performing activities under such sponsor's contract for the operation of its own prescription drug plan.

§ 423.2806 Affiliate status.

(a) *Ownership or control—(1) General rule.* An entity is an affiliate of a pharmacy benefit manager or Part D plan sponsor if it meets the requirements of any of paragraphs (a)(2) through (4) with respect to the pharmacy benefit manager or Part D plan sponsor.

(2) *Ownership relationship.* An entity has an ownership relationship with a pharmacy benefit manager or Part D plan sponsor if the entity and the pharmacy benefit manager or Part D plan sponsor are treated as members of a parent-subsidiary controlled group under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986.

(3) *Control relationship.* (i) An entity has a control relationship with a pharmacy benefit manager or Part D plan sponsor if either the entity or the pharmacy benefit manager or Part D plan sponsor has the power to materially determine or direct the material actions, policies, or decisions of the other entity, regardless of ownership percentage, through any of the following:

(A) The power to appoint, elect, or remove a majority of the other entity's governing body.

(B) Contractual veto, consent, or supermajority rights over material business decisions of the other entity.

(C) Contractual rights to appoint, direct, or remove senior officers of the other entity, or to direct the other entity's day-to-day operations through a management or administrative services agreement.

(D) Exclusive dealing, requirements contracts, or similar arrangements that, alone or together with other contractual or economic arrangements, give one entity practical authority to materially direct or constrain the other entity's material business decisions related to the Part D program.

(ii) Control includes indirect control exercised through one or more intermediary entities, assessed link by link through the chain of relationships.

(4) *Otherwise related in an ownership structure.* An entity is otherwise related in an ownership structure to a pharmacy benefit manager or Part D plan sponsor if it does not meet the requirements of paragraph (a)(2) or (3) of this section, but the relationship between the entity and a pharmacy benefit manager or Part D plan sponsor meets any of the following requirements in paragraphs (a)(4)(i) through (iv) of this section and

the relationship confers meaningful influence either to the entity or the pharmacy benefit manager or Part D plan sponsor.

(i) The entities are treated as members of a brother–sister controlled group under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986.

(ii) One entity holds a 10 percent or greater capital or profits interest in a joint venture, limited partnership, limited liability company, or comparable arrangement in which the other entity participates.

(iii) The totality of the structural features of the relationship confers meaningful influence by one entity over the other, notwithstanding the failure to satisfy the thresholds in paragraphs (a)(4)(i) through (ii) of this section.

(5) *General principles.* The following principles apply to paragraphs (a)(2) through (4) of this section:

(i) *Entity-form neutrality.* The term interest is measured by any of the following:

(A) Voting power or equity value for corporations.

(B) Capital or profits interest for partnerships and limited liability companies.

(C) Beneficial interest for trusts and unincorporated enterprises.

(ii) *Right-to-acquire rules.* The right to acquire an ownership interest that is exercisable within 60 days—through option, warrant, conversion right, or revocable proxy—is treated as a present holding of that interest.

(b) *Functional relationships.* An entity is an affiliate of a pharmacy benefit manager or Part D plan sponsor if it meets all of the following requirements with respect to the pharmacy benefit manager or Part D plan sponsor:

(1) Acts as a contractor, principal, or agent to such pharmacy benefit manager or Part D plan sponsor.

(2) Performs one or more PBM functions as a material part of its contractual services.

§ 423.2808 Part D plan sponsor contracts.

For plan years beginning on or after January 1, 2028, each contract entered into with a Part D plan sponsor under § 423.505 with respect to a prescription drug plan offered by such sponsor must provide that any pharmacy benefit manager acting on behalf of such sponsor has a written agreement with the Part D plan sponsor under which the pharmacy benefit manager, and any affiliates of such pharmacy benefit manager, as applicable, agree to the requirements described in §§ 423.2810, 423.2812, 423.2814, 423.2816, 423.2818, and 423.2820(b) and (c).

§ 423.2810 Pharmacy benefit manager and affiliate remuneration.

(a) *General.* Pharmacy benefit managers and any affiliates of such pharmacy benefit managers must not derive any remuneration with respect to any services provided on behalf of any entity or individual, in connection with the utilization of Part D drugs, from any such entity or individual, other than bona fide service fees, subject to paragraphs (b) through (d) of this section.

(b) *Bona fide service fees.* (1) *General rule.* A bona fide service fee is a flat dollar amount that meets all of the following:

(i) Reflects the fair market value, as defined in paragraph (e)(1) of this section, of a bona fide, itemized service actually performed on behalf of an entity.

(ii) Covers a service the entity would otherwise perform, or contract for, in the absence of the service arrangement, as described in paragraph (b)(2) of this section.

(iii) Is not passed on, in whole or in part, to a client or customer, regardless of whether the entity takes title to the drug.

(iv) Is not directly or indirectly based on, or contingent upon—

(A) Drug price, such as wholesale acquisition cost or a drug benchmark price (for example, average wholesale price);

(B) The amount of discounts, rebates, fees, or other remuneration—whether direct or indirect—with respect to Part D drugs dispensed to plan enrollees, except as permitted under paragraph (c) of this section;

(C) Coverage or formulary placement decisions, or the volume or value of any referrals or business generated between the parties to the arrangement; or

(D) Any amount or methodology prohibited under paragraph (b)(3) of this section.

(2) *Service qualification standard.* A service qualifies under paragraph (b)(1)(ii) of this section if it is a necessary or useful service of operational, administrative, clinical, financial, compliance, or programmatic value to the entity on whose behalf it is performed, such that the entity would perform the service itself or procure it from another party in the absence of the service arrangement.

(3) *Other prohibited amounts and methodologies.* The following amounts and methodologies are prohibited in the determination of a bona fide service fee:

(i) A pharmacy benefit manager, or an affiliate of such pharmacy benefit manager, may not require the party paying a bona fide service fee to pay any

additional fee—including any additional fee that otherwise would meet the requirements of a bona fide service fee under paragraph (b) of this section—in order to—

(A) Access the primary benefit of the itemized service; or

(B) Obtain sufficient information to provide oversight of the itemized service.

(ii)(A) A pharmacy benefit manager, or an affiliate of such pharmacy benefit manager, may not condition the availability of an itemized service on an agreement by the party with which the pharmacy benefit manager or an affiliate is contracting to provide remuneration for a separate service, as defined in paragraph (b)(3)(ii)(A) of this section.

(B) Separate service means an itemized service that the pharmacy benefit manager or an affiliate of such pharmacy benefit manager is not required to perform in order to provide the contracted itemized service.

(c) *Incentive payments.* (An incentive payment paid by a Part D plan sponsor to a pharmacy benefit manager or an affiliate of a pharmacy benefit manager that is performing services on behalf of such sponsor must be deemed a bona fide service fee (even if such payment does not otherwise meet the definition of bona fide service fee under § 423.2810(b)), if such payment meets all of the following criteria:

(1) Is a flat dollar amount.

(2) Is consistent with fair market value as defined under § 423.2810(e)(2).

(3) Is related to services actually performed by the pharmacy benefit manager or affiliate of such pharmacy benefit manager, on behalf of the Part D plan sponsor making such payment.

(4) Is made in connection with the utilization of Part D drugs.

(d) *Clarification on rebates and discounts used to lower costs for covered Part D drugs.*

(1) *General rule.* Manufacturer rebates, discounts, and other price concessions received by a pharmacy benefit manager or an affiliate of a pharmacy benefit manager from manufacturers—including price concessions calculated as a percentage of a drug's price—do not constitute a violation of the remuneration restriction under section 1860D–12(h)(1)(A)(i) of the Act, as described in this section § 423.2810, if the conditions set forth in paragraph (d)(2) of this section are satisfied.

(2) *Conditions.* To qualify for the exception in paragraph (d)(1) of this section, a rebate, discount, or other price concession must do all of the following:

(i) Be fully passed through to the Part D plan sponsor, as defined in § 423.2802.

(ii) Comply with all regulatory and subregulatory requirements related to direct and indirect remuneration (DIR) for manufacturer rebates, discounts, and other price concessions under Part D, including but not limited to the criteria in paragraph (d)(2)(iii) of this section.

(iii) Satisfy all applicable DIR compliance requirements, including but not limited to all of the following criteria:

(A) Accurately classified in the Summary and Detailed DIR Reports or any successor reporting mechanism required by CMS.

(B) Allocated to the appropriate plan, drug, NDC, utilization period, and plan year.

(C) Reported in the Summary and Detailed DIR Reports or any successor reporting mechanism required by CMS.

(D) Reflected in applicable Part D reconciliation and payment processes.

(E) Supported by records sufficient for audit.

(3) *Affiliates.* Manufacturer rebates, discounts, and other price concessions received by an affiliate of a pharmacy benefit manager are subject to the same conditions and treated in the same manner as manufacturer rebates, discounts, and other price concessions received directly by the pharmacy benefit manager for purposes of this section.

(4) *Non-qualifying arrangements.*

(i) Remuneration received from entities that are not manufacturers does not qualify for the exception under paragraph (d)(1) of this section.

(ii) A price concession that is retained by a pharmacy benefit manager or an affiliate of such pharmacy benefit manager, misclassified as a service fee, omitted from DIR reporting, or otherwise not reflected in applicable Part D reconciliation does not qualify for the exception under paragraph (d)(1) of this section unless corrected in accordance with CMS's applicable correction, reopening, reconciliation, or audit processes, including completion of any required pass-through, disgorgement, and corrected reporting.

(5) *Price concessions in cases where a Part D plan sponsor acts on its own behalf.* In cases where the Part D sponsor meets the performance standard for PBM status as described at § 423.2804(a)(2) and acts as a PBM on behalf of a prescription drug plan it offers, a price concession to such sponsor for such plan is deemed to satisfy the condition in paragraph (d)(2)(i) of this section, provided that such Part D plan sponsor receives 100

percent of the gross economic value of such price concession.

(e) *Fair market value* has the following meaning:

(1) For bona fide service fees, the cost incurred by the pharmacy benefit manager or affiliate of such pharmacy benefit manager to provide the itemized service plus a reasonable markup to the total cost, subject to paragraphs (e)(1)(i), (ii), and (iii) of this section.

(i) If any material portion of cost data is not available, the pharmacy benefit manager or affiliate of such pharmacy benefit manager must use an estimate of the expected cost of the itemized service until such time as sufficient observed cost data are available. Sufficient observed cost data will be considered available no later than 1 year after the bona fide service fee based on estimated costs is in effect.

(A) The estimate of the expected cost of the itemized service must be consistent with, if available, the cost incurred by the pharmacy benefit manager or affiliate of such pharmacy benefit manager to provide other itemized services, with reasonable adjustments as necessary to account for bona fide differences between the resources needed to perform each itemized service.

(B) [Reserved].

(ii) The cost of the itemized service is the sum of the allowable costs minus any applicable credits. A cost is allowable if it is reasonable, allocable, determined in accordance with generally accepted accounting principles (GAAP), supported by adequate documentation, and accorded consistent treatment.

(A) *Reasonable.* A reasonable cost cannot exceed an amount that a prudent person would incur under the circumstances prevailing when the decision to incur the cost was made. Consideration must be given to all of the following:

(1) Whether the cost is generally recognized as ordinary and necessary for the recipient's performance of the itemized service.

(2) The restraints or requirements imposed by such factors as sound business practices; arm's-length bargaining; and Federal, State, local, tribal, and other laws and regulations.

(3) The cost of comparable market transactions.

(4) Whether the cost represents a deviation from the recipient's established written policies and procedures for incurring costs.

(5) Whether the cost is subject to any bias due to overlap between the individuals who negotiate the bona fide service fee and the individuals who

negotiate remuneration or transactions other than bona fide service fees or incentive payments with the entity that pays the bona fide service fee.

(6) Whether the cost is comparable to costs incurred for similar services in the general, non-health care market.

(B) *Allocable.*

(1) In order for a cost to be allocable to an itemized service, the cost must be assignable to that itemized service in accordance with the relative benefits received. This standard can be met if the cost satisfies any of the following criteria:

(i) It is incurred specifically for that itemized service.

(ii) It benefits both the itemized service and other work of the recipient and can be distributed in proportions that may be approximated using reasonable methods.

(iii) It is necessary to the overall operation of the recipient and is assignable in part to the itemized service in accordance with these cost principles.

(2) The following principles apply to cost allocation:

(i) All itemized services which benefit from the recipient's indirect cost will receive an appropriate allocation of indirect costs.

(ii) A cost allocable to a particular itemized service may not be allocated to other itemized services.

(iii) If a cost benefits two or more itemized services in proportions that can be determined without undue effort or cost, the cost must be allocated to the itemized services based on the proportional benefit. If those proportions cannot be determined because of the interrelationship of the work involved, then, notwithstanding paragraph (c)(1)(ii)(B)(2)(ii) of this section, the costs may be allocated or transferred to itemized service on any reasonable documented basis.

(iv) Applicable credits refer to transactions that offset or reduce direct or indirect costs allocable to an itemized service. Examples of such transactions are purchase discounts, rebates or allowances, recoveries or indemnities on losses, insurance refunds or rebates, and adjustments of overpayments or erroneous charges. To the extent that such credits accruing to or received by the recipient relate to allowable costs, they must be credited to the itemized service either as a cost reduction or cash refund, as appropriate.

(3) The data and assumptions used to allocate costs must be updated not less than annually.

(iii) Any markup must be reasonable. Reasonable markup cannot exceed an amount that a prudent person would

apply under the circumstances prevailing when the decision regarding the amount of the markup was made. Consideration must be given to all of the following:

(A) The restraints or requirements imposed by such factors as sound business practices; arm's-length bargaining; and Federal, State, local, tribal, and other laws and regulations.

(B) Comparable market transactions.

(C) Whether the markup represents a deviation from the recipient's established written policies and procedures for determining markup.

(D) Whether the markup is subject to any bias due to overlap between the individuals who negotiate the bona fide service fee and the individuals who negotiate remuneration or transactions other than bona fide service fees or incentive payments with the entity that pays the bona fide service fee.

(E) Whether the markup is comparable to the markup applied to similar services in the general, non-health care market.

(2) For incentive payments, an amount reflective of comparable market transactions that generally reflect current market conditions.

(f) *Evaluation of remuneration agreements.*

(1) *General rule.* Components of subsets of remuneration arrangements, including fees or other forms of compensation paid to, received by, or retained by a pharmacy benefit manager or affiliate of such pharmacy benefit manager, between a pharmacy benefit manager or affiliate of such pharmacy benefit manager and any entity involved in the dispensing or utilization of Part D drugs, are subject to review by CMS in accordance with paragraph (f)(3) of this section.

(2) *Entities involved in dispensing or utilization.* For purposes of paragraph (f)(1) of this section, entities involved in the dispensing or utilization of Part D drugs include Part D plan sponsors, manufacturers, pharmacies, wholesalers, and any other entity CMS determines appropriate.

(3) *Review of remuneration.* CMS, in consultation with the HHS OIG, may review whether remuneration under an arrangement described in paragraph (f)(1) of this section is consistent with fair market value and otherwise complies with section 1860D–12(h) of the Act.

(4) *Summary of components of subsets of remuneration arrangements.*

(i) Each pharmacy benefit manager selected via the process described in paragraph (f)(8) of this section must submit a summary of components of subsets of remuneration arrangements to

CMS, inclusive of all components of remuneration agreements described in (f)(9) of this section, in the form and manner, and by the deadline, specified by CMS.

(ii) The summary of components of subsets of remuneration arrangements must identify each remuneration arrangement at a level sufficient to identify and classify each distinct remuneration structure.

(iii) For each remuneration arrangement or payment stream, the pharmacy benefit manager must include, as applicable, all of the following in the summary:

(A) The payer of the remuneration.

(B) The recipient of the remuneration.

(C) The affiliate status of both the payer and recipient in relation to the PBM.

(D) The applicable Part D plan sponsor, contract, and plan.

(E) The service or payment category for the remuneration.

(F) A brief description of the remuneration arrangement or payment stream.

(G) The total amount of remuneration paid, received, and retained by the recipient.

(H) The amount of remuneration attributable to the utilization of covered Part D drugs.

(I) The unit of payment or fee methodology used by the payer to determine the amount of remuneration.

(J) Whether the arrangement or payment stream covers multiple services, multiple entities, PBM functions and non-PBM functions, or both Part D and non-Part D lines of business, and, if applicable, information regarding these aspects of the arrangement or payment.

(K) Whether the arrangement or payment stream is bundled, and, if applicable, to include information regarding the services, products, and other components included in the bundle.

(L) Classification of the remuneration as one or more of the following:

(1) A bona fide service fee as described at § 423.2810(b).

(2) An incentive payment as described at § 423.2810(c).

(3) A rebate, discount, or other price concession fully passed through to the Part D plan sponsor as described at § 423.2810(d).

(4) An amount protected by the rule of construction under § 423.2810(i), including a flat dispensing fee, reimbursement or payment for ingredient costs, or a customary, industry-standard discount directly related to drug acquisition that is retained by a pharmacy or wholesaler.

(5) Other remuneration type.

(iv) The pharmacy benefit manager must include a crosswalk sufficient for CMS to identify the location where each of the data elements may be found in the remuneration arrangement.

(5) *Additional substantiation upon request.*

(i) CMS may require a pharmacy benefit manager to submit additional substantiation for selected remuneration arrangements, in the form, manner, and timeframe specified by CMS.

(ii) Additional substantiation may include, but is not limited to, each of the following:

(A) Cost support.

(B) Fair market value support.

(C) Allocation support.

(iii) For purposes of paragraph (e)(5)(ii)(A) of this section, cost data may include direct labor, labor rates, personnel or time allocation, technology costs, vendor costs, overhead allocation, direct and indirect administrative costs, and profit margin or markup.

(iv) For purposes of paragraph (e)(5)(ii)(B) of this section, fair market value support may include the fair market value methodology, key assumptions, valuation date, preparer, cost-plus analysis, comparable market data if used, and any third-party valuation materials.

(6) *Confidentiality.* Information submitted under this section is subject to the confidentiality protections in section 1860D–12(h)(6) of the Act and as described at § 423.2822, as applicable.

(7) *Responsibility for affiliate-held information.* A pharmacy benefit manager is responsible for obtaining from its affiliates and submitting to CMS information required under this section that is owned, held, or controlled by an affiliate of the pharmacy benefit manager.

(8) *Selection of pharmacy benefit managers.* CMS may select pharmacy benefit managers for submission of the summary of components of subsets of remuneration arrangements described at paragraph (f)(4) of this section by one or both of the following methods:

(i) *Data-based selection.* CMS may select pharmacy benefit managers based on review of the annual pharmacy benefit manager report described at § 423.2814 or other information available to CMS.

(ii) *Random selection.* CMS may select a random sample of pharmacy benefit managers in a form and manner specified by CMS.

(9) *Selection of Remuneration Arrangements.* For each PBM selected, CMS may select a sample of Part D plan sponsors with which the PBM has a written agreement to act on behalf of the

Part D plan sponsor. All remuneration agreements held by the PBM, as well as those held by a sample of any affiliates of such PBM (selected by CMS from the list of affiliates reported by the PBM under the annual report described at § 423.2814), with any individual or entity, under which the PBM or affiliate of such PBM receives remuneration for services in connection with the utilization of Part D drugs by enrollees in a prescription drug plan offered by such Part D plan sponsor must be included in the summary of components of subsets of remuneration arrangements described at (f)(4).

(g) *Disgorgement of remuneration to the Part D plan sponsor.* The pharmacy benefit manager must disgorge to the Part D plan sponsor any remuneration paid to such pharmacy benefit manager or an affiliate of such pharmacy benefit manager in violation of the requirements described at § 423.2810(a) for services in connection with the utilization of Part D drugs by enrollees in a prescription drug plan offered by such Part D plan sponsor, and must comply with the requirements described in paragraphs (g)(1), (2), and (3) of this section.

(1) The pharmacy benefit manager must disgorge any such remuneration to the Part D plan sponsor no later than the earlier of the following dates:

(i) Thirty days following the conclusion of an audit by the Part D plan sponsor, as allowed at § 423.2818, through which remuneration paid to the pharmacy benefit manager or affiliate of such pharmacy benefit manager in violation of the requirements described at § 423.2810(a) was found.

(ii) Thirty days following the end of the month in which the pharmacy benefit manager or affiliate of such pharmacy benefit manager identifies remuneration paid to the pharmacy benefit manager or affiliate of such pharmacy benefit manager in violation of the requirements at § 423.2810(a). If the pharmacy benefit manager or affiliate of such pharmacy benefit manager identifies remuneration paid to the pharmacy benefit manager or affiliate of such pharmacy benefit manager in violation of the requirements described at § 423.2810(a) during an audit by the Part D plan sponsor described in § 423.2818 and prior to the conclusion of such audit, 30 days following the end of the month in which the pharmacy benefit manager or affiliate of such pharmacy benefit manager identified remuneration paid to the pharmacy benefit manager or affiliate of such pharmacy benefit manager in violation of the requirements described at § 423.2810(a)

would be considered the earlier of the dates described in paragraphs (g)(1)(i) and (ii) of this section.

(2) The pharmacy benefit manager or affiliate of such pharmacy benefit manager must provide all of the following information to the Part D plan sponsor by the same deadline described in (g)(1) of this section:

(i) The amount of the remuneration in violation of the requirements described at § 423.2810(a).

(ii) The entity from which such remuneration was derived.

(iii) The entity that received such remuneration.

(iv) The nature of the violation.

(3)(i) The pharmacy benefit manager must enter into an agreement with any affiliate of such pharmacy benefit manager, under which the affiliate must identify and disgorge any remuneration paid to the affiliate in violation of the requirements described at § 423.2810(a).

(ii) The written agreement between the Part D plan sponsor and the pharmacy benefit manager must include the pharmacy benefit manager's attestation that the pharmacy benefit manager has entered into the written agreement described in paragraph (g)(3) with any affiliate of such pharmacy benefit manager.

(h) *In connection with the utilization of Part D drugs.* (1) Remuneration is in connection with the utilization of Part D drugs if the remuneration relates to the prescribing, dispensing, furnishing, coverage, reimbursement, or management of Part D drugs, including activities that directly or indirectly influence or determine such utilization.

(2) For services supporting multiple lines of business, only the portion of remuneration allocable to the utilization of Part D drugs under a Part D plan is considered.

(i) *Rule of construction.* (1) Nothing in § 423.2810 prohibits flat dispensing fees or reimbursement or payment for ingredient costs, including customary, industry-standard discounts directly related to drug acquisition that are retained by pharmacies or wholesalers, to entities that acquire or dispense prescription drugs.

(2) Nothing in § 423.2810 modifies regulatory requirements or subregulatory program instructions or guidance related to pharmacy payment, reimbursement, or dispensing fees.

§ 423.2812 Transparency regarding guarantees and cost performance evaluations.

(a) *General.* (1) For purposes of calculating or otherwise evaluating pharmacy benefit manager performance against pricing guarantees or similar

cost performance measurements related to rebates, discounts, price concessions, or net costs, the pharmacy benefit manager must define, interpret, and apply in a fully transparent and consistent manner any terms that are integral to the evaluation or calculation of cost performance under such agreement, including but not limited to 'generic drug', 'brand name drug', 'specialty drug', 'rebate', and 'discount'. The following requirements apply to the definitions of 'generic drug' and 'brand name drug' for purposes of this paragraph (1):

(i) Generic drug must be defined in a manner consistent with the definition of the term under § 423.4 or a successor regulation.

(ii) Brand name drug must be defined in a manner consistent with the definition of the term under § 423.4 or a successor regulation.

(2) The pharmacy benefit manager must identify any drugs, claims, or price concessions excluded from any pricing guarantee or other cost performance measure in a clear and consistent manner. Where a pricing guarantee or other cost performance measure is based on a pricing benchmark other than the wholesale acquisition cost (as defined in section 1847A(c)(6)(B) of the Act) of a drug, the pharmacy benefit manager must calculate and provide a wholesale acquisition cost-based equivalent to the pricing guarantee or other cost performance measure.

(b) *Terms defined in written agreement.* (1) *General.* The definitions of any terms in accordance with paragraph (a) of this section must be included in the written agreement between the pharmacy benefit manager and the Part D plan sponsor.

(2) *Information provided.* Upon request of the Part D plan sponsor, but not less than annually, the pharmacy benefit manager must provide to the Part D plan sponsor a list of drugs, including the NDC-11 or NDC-12 identifier of each drug, included in the categories of drugs, such as generic drug, brand name drug, or specialty drug, for which pharmacy benefit manager performance against pricing guarantees or similar cost performance metrics is measured.

(c) *Drugs, claims, or price concessions excluded from cost performance measures.* Upon request of the Part D plan sponsor, but not less than annually, the pharmacy benefit manager must provide to the Part D plan sponsor the list of drugs, claims, or price concessions excluded from any pricing guarantee or other cost performance measure with sufficient information for the Part D plan sponsor to clearly

identify such drugs, claims, or price concessions—including NDC–11 or NDC–12 identifiers for such drugs, identifying information about claims such as date of service and beneficiary identifier, and information about such price concessions such as the amount of the price concession and the drug(s) to which it applies.

(d) *Wholesale acquisition cost source.* Where a pricing guarantee or other cost performance measure is based on a pricing benchmark other than the wholesale acquisition cost and the pharmacy benefit manager calculates and provides a wholesale acquisition cost-based equivalent to the pricing guarantee or other cost performance measure, the pharmacy benefit manager must disclose the source of the wholesale acquisition cost used.

§ 423.2814 Annual pharmacy benefit manager reporting requirements.

(a) *General.* Not later than July 1 of each year, beginning in 2028, the pharmacy benefit manager must submit a report to the Part D plan sponsor and to CMS containing the information described at paragraph (d) of this section.

(1) Pharmacy benefit managers must submit this report to CMS in a form and manner specified by CMS.

(b) *Format.* The annual report must be in the format specified by CMS through program instruction.

(c) *Definitions.* As used in this section, the following definitions apply:

30-day supply means the amount of such drug equal to the average 30-day equivalent supply, as described at § 423.104(d)(2)(iv)(A)(2), across all PDE records for such drug for enrollees in such plan in such plan year. If the pharmacy benefit manager does not have access to PDE records for such plan for such plan year, an estimated amount per 30-day supply based on dosage information on the most recent label approved by the Food and Drug Administration (FDA) or other reasonable assumptions may be used.

90-day supply means 3 times the 30-day supply of the drug, as defined under paragraph (c) of this section.

Affiliate has the meaning described at § 423.2802.

Affiliate, such as a pharmacy or other entity that acquires prescription drugs, that initially acquires the drug means an affiliate that, during any point in the plan year, acquired any amount of such drug that had not previously been acquired by an affiliate of the same pharmacy benefit manager (or, in the event that the manufacturer of the drug is an affiliate of the pharmacy benefit manager and sold the drug to another

affiliate of the same pharmacy benefit manager, such affiliate that acquired the drug from such manufacturer). If multiple affiliates meet such criteria, all such affiliates must be treated as the affiliate that initially acquires the drug, and the acquisition cost must be averaged across all such affiliates.

Average acquisition cost means the average cost, per dosage unit, to the entity to acquire the drug, from all sources from which such entity acquired the drug during such plan year, both in aggregate and by dispensing channel.

Average National Average Drug Acquisition Cost (NADAC): the sum of the products of each NADAC in effect for such drug during such plan year and the quotient of the number of days in which such NADAC was in effect divided by the number of days any NADAC was in effect during such year.

Average pharmacy reimbursement amount paid by the plan for the drug means the average of the amount paid by the plan per 30-day supply of the drug, across all fills of the drug during such plan year.

Average wholesale acquisition cost means the sum of the products of each wholesale acquisition cost (WAC) in effect for such drug during such plan year and the quotient of the number of days in which such WAC was in effect divided by the number of days any WAC was in effect during such year.

Average wholesale price (AWP) means the sum of the products of each AWP in effect for such drug during such plan year and the quotient of the number of days in which such AWP was in effect divided by the number of days any AWP was in effect during such year.

Course of treatment has the meaning of “typical course of treatment” defined at paragraph (c) of this section.

Currently marketed biosimilar biological product means a biosimilar biological product licensed under section 351(k) of the Public Health Service Act that meets either of the following criteria:

- (i) Is listed in the Purple Book with a marketed status of “Rx”; or
- (ii) Is listed in the product file of the National Drug Code Directory with either a blank end marketing date or an end marketing date in the future.

Currently marketed generic drug means a generic drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act that meets either of the following criteria:

- (i) Is listed in the Orange Book and is not discontinued; or
- (ii) Is listed in the product file of the National Drug Code Directory with

either a blank end marketing date or an end marketing date in the future.

Day's supply means the amount of such drug represented by the average day's supply across all fills in prescription drug event (PDE) data for such drug for such Part D plan sponsor and pharmacy benefit manager in such plan year. If the pharmacy benefit manager does not have access to PDE data, an estimated amount per day's supply based on dosage information on the most recent label approved by the FDA or other reasonable assumptions may be used.

Dispensing channel means the dispensing channel as represented by the National Council for Prescription Drug Programs (NCPDP) pharmacy dispenser type code. If there are multiple NCPDP pharmacy dispenser type codes, the beneficiary's residence type should be used to determine the appropriate dispensing channel.

Dosage unit means the amount of such drug represented by its NCPDP unit type.

Drug means a drug or biological product associated with a unique NDC–11 or NDC–12 identifier.

Generic or non-proprietary name means the name that matches the non-proprietary name data element in the NDC Directory product file.

National Drug Code means the unique, 11-digit or 12-digit identifier of the National Drug Code submitted by the Food and Drug Administration to the Drug Registration and Listing System for a drug product, also known as an NDC–11 or NDC–12 code.

Percentage of total prescriptions that were dispensed by pharmacies that are an affiliate of the pharmacy benefit manager for each drug means the quotient of the number of 30-day supplies of such drug (as defined in paragraph (c) of this section) dispensed by pharmacies that are an affiliate of the pharmacy benefit manager to an enrollee of such Part D plan sponsor in such plan year divided by the number of 30-day supplies of such drug dispensed by any pharmacy to an enrollee of such Part D plan sponsor in such plan year.

Pharmacy benefit manager has the meaning described at § 423.2802.

Pharmacy benefit management services has the meaning of “PBM function” described at § 423.2802.

Pharmacy network means the pharmacy network inclusive of both preferred and non-preferred pharmacies.

Remuneration related to utilization of Part D drugs means remuneration that meets the requirements defined at § 423.2810(g).

Total manufacturer-derived revenue, inclusive of bona fide service fees, attributable to the drug and retained by the pharmacy benefit manager and any affiliate of such pharmacy benefit manager means revenue that is either paid directly from a manufacturer to the pharmacy benefit manager or affiliate or paid directly from a manufacturer to any entity and passed through in whole or in part from that entity, as well as from any other additional entities, and is received by the pharmacy benefit manager or affiliate. Only the amount of revenue received by the pharmacy benefit manager and any affiliate of such pharmacy benefit manager should be included in this amount; revenue retained by other entities and not passed through should not be included.

Typical course of treatment means the amount of such drug estimated by the pharmacy benefit manager to be associated with a typical course of treatment based on dosage information on the most recent label approved by FDA, using reasonable assumptions for variable factors such as patient weight or other factors affecting dosing, which must be reported by pharmacy benefit managers as part of the data submission. For drugs or biological products used to treat chronic conditions for which the typical course of treatment is indefinite, the typical amount of such drug associated with 1 year of treatment may be used, and pharmacy benefit managers must indicate this methodology in the reasonable assumptions.

(d) *Information to be provided.* The following information must be included in the annual report, with respect to the most recent complete plan year preceding the deadline for the annual report specified at § 423.2814(a) for paragraphs (d)(1) through (10) of this section and with respect to June 1 of the prior calendar year through May 31 of the current calendar year for paragraph (d)(11) of this section:

(1) A list of all drugs covered by the plan that were dispensed including, with respect to each such drug, all of the following:

(i) The brand name, generic or non-proprietary name, and National Drug Code.

(ii) The number of plan enrollees for whom the drug was dispensed, the total number of prescription claims for the drug (including original prescriptions and refills, counted as separate claims), and the total number of dosage units of the drug dispensed.

(iii) The number of prescription claims described in paragraph (d)(1)(ii) of this section by each type of dispensing channel through which the drug was dispensed, including retail,

mail order, specialty pharmacy, long term care pharmacy, home infusion pharmacy, or other types of pharmacies or dispensers.

(iv) The average wholesale acquisition cost, listed as cost per day's supply, cost per dosage unit, and cost per typical course of treatment (as applicable).

(v) The average wholesale price for the drug, listed as price per day's supply, price per dosage unit, and price per typical course of treatment (as applicable).

(vi) The total out-of-pocket spending by plan enrollees on such drug after application of any benefits under the plan, including plan enrollee spending through copayments, coinsurance, and deductibles.

(vii) The total rebates paid by the manufacturer on the drug as reported under the Detailed DIR Report (or any successor report) submitted by such sponsor to CMS.

(viii) All other direct or indirect remuneration on the drug as reported under the Detailed DIR Report (or any successor report) submitted by such sponsor to CMS.

(ix) The average pharmacy reimbursement amount paid by the plan for the drug in the aggregate and disaggregated by dispensing channel identified in paragraph (d)(1)(iii) of this section.

(x) The average National Average Drug Acquisition Cost (NADAC).

(xi) Total manufacturer-derived revenue, inclusive of bona fide service fees, attributable to the drug and retained by the pharmacy benefit manager and any affiliate of such pharmacy benefit manager.

(2) In the case of a pharmacy benefit manager that has an affiliate that is a retail, mail order, or specialty pharmacy, with respect to drugs covered by such plan that were dispensed, the following information:

(i) The percentage of total prescriptions that were dispensed by pharmacies that are an affiliate of the pharmacy benefit manager for each drug.

(ii) The interquartile range of the total combined costs paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply for each drug dispensed by pharmacies that are not an affiliate of the pharmacy benefit manager and that are included in the pharmacy network of such plan.

(iii) The interquartile range of the total combined costs paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply for each drug dispensed by pharmacies that are an

affiliate of the pharmacy benefit manager and that are included in the pharmacy network of such plan.

(iv) The lowest total combined cost paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, for each drug that is available from any pharmacy included in the pharmacy network of such plan.

(v) The difference between the average acquisition cost of the affiliate, such as a pharmacy or other entity that acquires prescription drugs, that initially acquires the drug and the amount reported under § 423.2814(d)(1)(x) for each drug.

(vi) A list inclusive of the brand name, generic or non-proprietary name, and National Drug Code of covered Part D drugs subject to an agreement with a covered entity under section 340B of the Public Health Service Act for which the pharmacy benefit manager or an affiliate of the pharmacy benefit manager had a contract or other arrangement with such a covered entity in the service area of such plan.

(3) Where a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (referred to in this subclause as the listed drug) is covered by the plan, the following information:

(i) A list of currently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act in accordance with an application that references such listed drug that are not covered by the plan, are covered on the same formulary tier or a formulary tier typically associated with higher cost-sharing than the listed drug, or are subject to utilization management that the listed drug is not subject to.

(ii) Whether each such generic drug is private label or not.

(iii) The estimated average beneficiary cost-sharing under the plan for a 30-day supply of the listed drug.

(iv) Where a currently marketed generic drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act in accordance with an application that references such listed drug is on a formulary tier typically associated with higher cost-sharing than the listed drug, the average beneficiary cost-sharing under the plan for a 30-day supply of each such generic drug.

(v) Where a generic drug listed under paragraph (d)(3)(i) of this section is on a formulary tier typically associated with higher cost-sharing than the listed drug, the estimated average cost-sharing that a beneficiary would have paid for a 30-day supply of each of the generic drugs described in paragraph (d)(3)(i) of this section, had the plan provided

coverage for such drugs on the same formulary tier as the listed drug.

(vi) A written justification for providing more favorable coverage of the listed drug than the generic drugs described in paragraph (d)(3)(i) of this section.

(vii) The number of currently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act in accordance with an application that references such listed drug.

(viii) Where the listed drug is subject to prior authorization under the plan, the average denial rate of prior authorizations submitted for the listed drug during the plan year.

(ix) Where a currently marketed generic drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act in accordance with an application that references such listed drug is subject to prior authorization under the plan, the average denial rate of prior authorizations submitted for each such generic drug during the plan year.

(x) Where the listed drug is subject to any utilization management tool other than prior authorization under the plan, a brief description of each such utilization management tool.

(xi) Where the listed drug is subject to any utilization management tool other than prior authorization, the average denial rate of each such utilization management tool during the plan year.

(xiii) Where a currently marketed generic drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act in accordance with an application that references such listed drug is subject to the same utilization management tool (other than prior authorization) as the listed drug, the average denial rate of each such utilization management tool during the plan year.

(4) Where a reference product (as defined in section 351(i) of the Public Health Service Act) is covered by the plan, the following information:

(i) A list of currently marketed biosimilar biological products licensed under section 351(k) of the Public Health Service Act in accordance with an application that refers to such reference product that are not covered by the plan, are covered on the same formulary tier or a formulary tier typically associated with higher cost-sharing than the reference product, or are subject to utilization management that the reference product is not subject to.

(ii) Whether each such biosimilar biological product is private label or not.

(iii) The estimated average beneficiary cost-sharing under the plan for a 30-day supply of the reference product.

(iv) Where a currently marketed biosimilar biological product licensed under section 351(k) of the Public Health Service Act in accordance with an application that refers to such reference product is on a formulary tier typically associated with higher cost-sharing than the reference product, the average beneficiary cost-sharing under the plan for a 30-day supply of each such biosimilar biological product.

(v) Where a biosimilar biological product listed under paragraph (d)(3)(i) of this section is on a formulary tier typically associated with higher cost-sharing than the reference product, the estimated average cost-sharing that a beneficiary would have paid for a 30-day supply of each of the biosimilar biological products described in paragraph (d)(3)(i) of this section, had the plan provided coverage for such products on the same formulary tier as the reference product.

(vi) A written justification for providing more favorable coverage of the reference product than the biosimilar biological products described in paragraph (d)(3)(i) of this section.

(vii) The number of currently marketed biosimilar biological products licensed under section 351(k) of the Public Health Service Act, in accordance with an application that refers to such reference product.

(viii) Where the reference product is subject to prior authorization under the plan, the average denial rate of prior authorizations submitted for the reference product during the plan year.

(ix) Where a currently marketed biosimilar biological product licensed under section 351(k) of the Public Health Service Act in accordance with an application that refers to such reference product is subject to prior authorization under the plan, the average denial rate of prior authorizations submitted for each such biosimilar biological product during the plan year.

(x) Where the reference product is subject to any utilization management tool other than prior authorization under the plan, a brief description of each such utilization management tool.

(xi) Where the reference product is subject to any utilization management tool other than prior authorization, the average denial rate of each such utilization management tool for the reference product during the plan year.

(xii) Where a currently marketed biosimilar biological product licensed under section 351(k) of the Public Health Service Act in accordance with

an application that refers to such reference product is subject to the same utilization management tool (other than prior authorization) as the listed drug, the average denial rate of each such utilization management tool for each such biosimilar biological product during the plan year.

(5) Total gross spending on covered Part D drugs by the plan, not net of rebates, fees, discounts, or other direct or indirect remuneration.

(6) The total amount retained by the pharmacy benefit manager or an affiliate of such pharmacy benefit manager in remuneration related to utilization of Part D drugs under that plan, inclusive of bona fide service fees.

(7) The total spending on covered Part D drugs net of rebates, fees, discounts, or other direct and indirect remuneration by the plan.

(8) An explanation of any benefit design parameters under such plan that encourage plan enrollees to fill prescriptions at pharmacies that are an affiliate of such pharmacy benefit manager, such as mail and specialty home delivery programs, and retail and mail auto-refill programs.

(9) The following information:

(i) A list of all brokers, consultants, advisors, and auditors that receive compensation from the pharmacy benefit manager or an affiliate of such pharmacy benefit manager for referrals, consulting, auditing, or other services offered to Part D plan sponsors related to pharmacy benefit management services.

(ii) The amount of compensation provided by such pharmacy benefit manager or affiliate to each such broker, consultant, advisor, and auditor.

(iii) The methodology for calculating the amount of compensation provided by such pharmacy benefit manager or affiliate, for each such broker, consultant, advisor, and auditor.

(10) A list of all affiliates of the pharmacy benefit manager.

(11) The following information about any funds disgorged from the pharmacy benefit manager or any affiliates of such pharmacy benefit manager to the Part D plan sponsor consistent with the requirements at § 423.2810(f)(2) from June 1 of the calendar year preceding the deadline for the annual report specified at § 423.2814(a) through May 31 of the calendar year of the deadline for the annual report specified at § 423.2814(a):

(i) The amounts disgorged to the Part D plan sponsor.

(ii) The date of receipt of disgorged funds by the Part D plan sponsor.

(iii) The entity from which such remuneration was derived.

(iv) The entity that received such remuneration.

(vi) The nature of the violation.

(e) *Summary document.* The summary document described at section 1860D–12(h)(1)(C)(i)(XI) of the Act is the annual report in the format specified by CMS as described at § 423.2814(b).

(f) *Certification.* The annual report must be certified by the Chief Executive Officer, Chief Financial Officer, or General Counsel of such pharmacy benefit manager, or an individual delegated the authority to sign on behalf of one of these officers, who reports directly to the officer.

§ 423.2816 Written explanation of contracts or agreements with manufacturers.

(a) *General.* (1) Not later than 30 days after the finalization of any contract or agreement between a pharmacy benefit manager or an affiliate of such pharmacy benefit manager and a manufacturer (or subsidiary, agent, or entity affiliated with such manufacturer) that makes rebates, discounts, payments, or other financial incentives related to one or more covered Part D drugs or other prescription drugs, as applicable, of the manufacturer directly or indirectly contingent upon coverage, formulary placement, or utilization management conditions on any other covered Part D drugs or other prescription drugs, as applicable, such pharmacy benefit manager must submit to the Part D plan sponsor a written explanation of such contract or agreement.

(2) The written explanation must include the manufacturer subject to the contract or agreement, all covered Part D drugs and other prescription drugs, as applicable, subject to the contract or agreement and the manufacturers of such drugs, and a high-level description of the terms of such contract or agreement and how such terms apply to such drugs.

(b) *Definition—Other prescription drugs* means prescription drugs covered as supplemental benefits under the Part D program or prescription drugs paid outside of the Part D program.

(c) *High-level description of terms.* The high-level description of the terms of such contract or agreement must describe the methodology by which the rebates, discounts, payments, or other financial incentives related to one or more covered Part D drugs or other prescription drugs is directly or indirectly contingent on coverage, formulary placement, or utilization management conditions on any other covered Part D drugs or other prescription drugs.

(d) *Certification.* The written explanation must be certified by the Chief Executive Officer, Chief Financial Officer, or General Counsel of such pharmacy benefit manager, or affiliate of such pharmacy benefit manager, as applicable, or an individual delegated the authority to sign on behalf of one of these officers, who reports directly to the officer.

§ 423.2818 Audit rights.

(a) *General.* Not less than annually, at the request of the Part D plan sponsor, the pharmacy benefit manager must allow for an audit of the pharmacy benefit manager to ensure compliance with all terms and conditions of the written agreement required under § 423.2808 and the accuracy of data reported under § 423.2814.

(b) *Auditor selection.* The Part D plan sponsor must have the right to select an auditor, and the pharmacy benefit manager may not impose any limitations on the selection of such auditor.

(c) *Provision of information.* (1) *General.* The pharmacy benefit manager must make available to such auditor all records, data, contracts, and other information necessary to confirm the accuracy of information reported under § 423.2814, subject to reasonable restrictions on how such information must be reported to prevent redisclosure of such information.

(2) *Reasonable restrictions.*

Reasonable restrictions—

(i) May address the types of records, data, contracts, and other information to be reported; the manner of reporting such information; and the use, disclosure, and dispensing of such information by the auditor and the Part D plan sponsor; and

(ii) May not include requirements that wholly prevent the auditor from accessing records, data, contracts, and other information that are necessary to confirm the accuracy of information reported under § 423.2814.

(d) *Timing.* The pharmacy benefit manager must provide such information and other information, data, and records relevant to the audit to such auditor within 6 months of the initiation of the audit and respond to requests for additional information from such auditor within 30 days after the request for additional information.

(e) *Affiliate information.* The pharmacy benefit manager is responsible for providing to such auditor information required to be reported under § 423.2814 or under § 423.2818(c) that is owned or held by an affiliate of such pharmacy benefit manager.

(f) *Timing for audits of affiliate pharmacy benefit managers.* If a pharmacy benefit manager providing PBM functions on behalf of the Part D plan sponsor is an affiliate of such Part D plan sponsor, the Part D plan sponsor must conduct an audit of such pharmacy benefit manager annually.

§ 423.2820 Compliance and enforcement.

(a) *Disgorgement of remuneration to CMS.* (1) A Part D plan sponsor must disgorge any amounts disgorged to the Part D plan sponsor by a pharmacy benefit manager or affiliate of such pharmacy benefit manager under § 423.2810(g) to CMS, in a form and manner determined by CMS.

(2) CMS utilizes the information at § 423.2814(d)(11) provided by pharmacy benefit managers under § 423.2814 in order to effectuate disgorgement of funds from Part D plan sponsors to CMS for deposit into the Federal Supplementary Medical Insurance Trust Fund, within the quarter (3 months) that starts on the July 1 data submission deadline at § 423.2814(a).

(b) *Civil money penalty (CMP) pass-through.* The pharmacy benefit manager or affiliate of such pharmacy benefit manager must reimburse the Part D plan sponsor for any CMP imposed on the Part D plan sponsor as a result of the failure of the pharmacy benefit manager or affiliate of such pharmacy benefit manager to meet the requirements of section 1860D–12(h)(1) of the Act that are applicable to such pharmacy benefit manager or such affiliate under the agreement.

(c) *Punitive remedies for breach of contract between Part D plan sponsor and pharmacy benefit manager.* The pharmacy benefit manager or affiliate of such pharmacy benefit manager must be subject to punitive remedies for breach of contract for failure to comply with the requirements applicable under section 1860D–12(h)(1) of the Act.

(d) *Reporting of alleged violations.* Alleged violations of the requirements at §§ 423.2810(a) and 423.2814(a) may be reported to CMS on a confidential basis by manufacturers, Part D plan sponsors, pharmacies, and other entities that have contractual relationships with pharmacy benefit managers or affiliates of such pharmacy benefit managers in a form and manner specified by CMS.

(e) *Anti-retaliation and anti-coercion.* Consistent with applicable Federal or State law, a Part D plan sponsor must not do any of the following:

(i) Retaliate against an individual or entity for reporting an alleged violation under paragraph (d) of this section.

(ii) Coerce, intimidate, threaten, or interfere with the ability of an

individual or entity to report any such alleged violations.

(f) *Certificate of compliance.*

Beginning with the contract certification cycle for plan year 2028 and annually thereafter, each Part D plan sponsor must furnish a certificate of compliance with section 1860D–12(h) of the Act in a form and manner specified by CMS.

§ 423.2822 Confidentiality and restriction on use of information.

(a) *Definition*—For purposes of this section, *available for purchase* means available—

- (1) In exchange for remuneration; and
- (2) Through an agreement for which the purpose is the provision of such information.

(b) *Confidentiality.* Information disclosed by a pharmacy benefit manager, an affiliate of a pharmacy benefit manager, a Part D plan sponsor, or a pharmacy under section 1860D–12(h) of the Act that is not otherwise publicly available or available for

purchase may not be disclosed by the Secretary or a Part D plan sponsor receiving the information, except that the Secretary may disclose the information for any of the following purposes:

- (1) To carry out Part D of Title XVIII of the Act.
- (2) To permit the Comptroller General to review the information provided.
- (3) To permit the Director of the Congressional Budget Office to review the information provided.
- (4) To permit the Executive Director of the Medicare Payment Advisory Commission to review the information provided.
- (5) To permit the Attorney General to conduct oversight and enforcement.
- (6) To provide to the Inspector General of HHS in accordance with its authorities under the Inspector General Act of 1978 (section 406 of title 5, United States Code), and other applicable statutes.

(c) *Restriction on use of information.* The Secretary, the Comptroller General, the Director of the Congressional Budget Office, and the Executive Director of the Medicare Payment Advisory Commission must not report on or disclose information disclosed in accordance with paragraph (b) of this section to the public in a manner that would identify any of the following:

- (1) A specific pharmacy benefit manager, affiliate, pharmacy, manufacturer, wholesaler, Part D plan sponsor, or plan.
- (2) Contract prices, rebates, discounts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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Part III

Department of Energy

Federal Energy Regulatory Commission

18 CFR Parts 2, 153, and 375

Authorizations for Certain Activities at Liquefied Natural Gas Plants;
Proposed Rule

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 2, 153, and 375

[Docket No. RM26–2–001]

RIN 1902–AG43

Authorizations for Certain Activities at Liquefied Natural Gas Plants

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission proposes to revise its regulations to establish procedures for authorizing activities at liquefied natural gas plants without

case-specific authorization orders under sections 3 or 7 of the Natural Gas Act.

DATES: Comments are due December 21, 2026.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways. Electronic filing through <http://www.ferc.gov>, is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.
- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.
- *Mail via US Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, Secretary of the Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

The Request for Comments section of this document contains more detailed filing procedures.

FOR FURTHER INFORMATION CONTACT: Danielle Elefritz (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8767
Andrew Kohout (Technical Information), Office of Energy Projects, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8053.

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1. The Federal Energy Regulatory Commission (Commission) in this notice of proposed rulemaking (NPR) proposes to amend its regulations to establish procedures for authorizing activities at liquefied natural gas (LNG) plants without the need for operators to file case-specific applications or for the Commission to issue case-specific orders under sections 3 or 7 of the Natural Gas Act (NGA).¹ This NPR includes proposed revisions to Parts 2, 153, and 375 of the Commission’s regulations.

I. Background

A. What is an LNG plant?

2. An LNG plant is a collection of facilities where natural gas is processed and cooled to about –260 °F until it becomes a liquid and is stored for later delivery, or where LNG is produced or delivered and stored for later regasification. Liquefying the gas dramatically reduces its volume (by about 600 times), making it easier and more economical to store and transport in bulk, especially by ocean-going marine vessels. Broadly, there are three types of LNG plants subject to the Commission’s jurisdiction: (1) LNG export terminals; (2) LNG import terminals; and (3) LNG facilities that receive natural gas, produce and store

LNG, and regasify it to deliver in interstate commerce.

3. For LNG export terminals, the LNG plant typically receives natural gas from a pipeline and processes it through a series of integrated systems—including feed-gas handling, pretreatment, liquefaction, and storage—to produce and store LNG. From there, the LNG is transferred to a marine vessel for export.

4. For LNG import terminals, the LNG plant typically receives LNG from a marine vessel and stores that LNG to regasify it in vaporization facilities, then sends out the natural gas to a pipeline or end user.²

¹ 15 U.S.C. 717b; 717f.

² The Commission would also have jurisdiction over an LNG terminal operating in interstate commerce where the LNG is received or sent out via waterborne vessel. *Id.* 717a(11).

5. LNG plants operating in interstate commerce are typically peak shaving plants that receive and liquefy natural gas during low demand periods, store it as LNG, and then regasify the LNG and send out the gas to an interstate pipeline during peak demand periods.

6. An LNG plant is composed of two distinct categories of facilities: LNG facilities and auxiliary systems. LNG facilities are those components of an LNG plant that receive, unload, load, store, transport, gasify, liquefy, or process natural gas. LNG facilities include, but are not limited to:³

(1) feed gas facilities, which include metering stations to receive natural gas; processing vessels to remove water and particulate matter; and compression, pressure regulation, and heating and cooling equipment;

(2) pretreatment facilities, which include equipment to remove carbon dioxide, sulfur compounds, mercury, water, or other impurities from the natural gas to safely and reliably liquefy the natural gas;

(3) natural gas liquid (NGL) facilities to extract or remove NGLs from natural gas,⁴ store NGLs, and use them as part of refrigerant makeup in liquefaction facilities or fuel gas for fired equipment, or to transfer them to truck, rail, or marine loading facilities or send them out in pipelines;

(4) heavy hydrocarbon condensate facilities to extract or remove condensates from natural gas, store condensates, and transfer them to truck, rail, or marine loading facilities, or send them out through pipelines, or re-vaporize condensates to use as fuel gas;

(5) liquefaction facilities used to safely and reliably liquefy the natural gas into LNG and transfer it through piping prior to entering the LNG storage facilities;⁵

(6) LNG storage facilities, including piping and valves used to fill the LNG tanks or vessels, and piping, valves, and in-tank pumps used to withdraw the LNG and transfer it to marine, truck, or rail loading or unloading transfer facilities or vaporization facilities;

(7) marine transfer facilities, including transfer arms, hoses, piping and valves, and other components used to unload or load marine vessels;

(8) truck and rail transfer facilities, including transfer arms, hoses, piping and valves, and other components used to unload or load truck or rail cars;

(9) vaporization or regasification facilities to convert the LNG back into natural gas prior to being sent out in a pipeline or to an end user;

(10) sendout gas conditioning facilities to meet pipeline quality specifications for the sendout gas; and

(11) sendout facilities, including sample stations and metering stations to measure the composition, flow, or other characteristics of the natural gas being sent out to a pipeline.

7. Auxiliary systems are those components of an LNG plant that are not LNG facilities but are necessary to support safe and reliable operation of the plant. Auxiliary systems include, but are not limited to:

(1) vapor handling systems to receive, process, and deliver boiloff gas from LNG containers, flash gas from process vessels, and any vapor generated or displaced from truck, rail, or marine transfer facilities;

(2) fuel gas systems to deliver natural gas to fired equipment;

(3) nitrogen and inert gas systems to unload, produce, and store nitrogen to create an inert nonflammable atmosphere where flammable fluids are handled;

(4) plant, utility, and instrument air systems to supply pneumatic pressure used by valve actuators and other equipment or tools;

(5) utility water systems to store and supply water used by power generation, boilers, heat exchangers, and other components;

(6) power generation and electrical systems, including any onsite main gas turbine, heat recovery steam generators, and emergency backup diesel engine generators, used to generate and supply power;

(7) emission control systems to reduce, control, capture, or transport air emissions;

(8) cathodic protection systems;

(9) relief valve and flare/vent systems used to safely and reliably discharge effluent from releases;

(10) security systems;

(11) spill containment systems used to contain any hazardous liquid spills from components and keep spill containment systems free of stormwater;

(12) passive protection systems, including cryogenic spill protection, vapor barriers, blast walls, passive fire protection, firewalls, radiant heat shields, foam glass blocks, or other systems to prevent cascading damage from hazardous fluid releases;

(13) hazard detection systems;

(14) hazard control systems used to extinguish or control fires;

(15) firewater systems;

(16) structural support systems;

(17) natural hazard mitigation used to monitor, measure, record, or protect LNG plant facilities and components from natural hazards; and

(18) emergency response systems, including any fire brigade buildings and apparatus, used to house and respond to hazardous fluid releases.

B. Existing Statutory and Regulatory Framework for the Commission's Authorization and Regulation of LNG Plants

8. The Commission regulates the siting, construction, expansion, and operation of LNG plants pursuant to sections 3 and 7 of the NGA. Section 3(a) provides for Federal jurisdiction over the siting, construction, expansion, and operation of facilities used to export or import natural gas.⁶ Section 3(e)(1) states that “[t]he Commission shall have the exclusive authority to approve or deny an application for the siting, construction, expansion, or operation of an LNG terminal.”⁷ And under section 7(c), the Commission issues certificates of public convenience and necessity for the construction and operation of natural gas and LNG facilities used for the transportation of natural gas in interstate commerce.⁸ Under both section 3 and section 7, the Commission has the authority to include terms and conditions in any order authorizing an LNG plant.⁹

9. The NGA also includes additional requirements that must be met prior to authorizing the construction of LNG terminals under section 3.¹⁰ Consistent with section 3A(a),¹¹ the Commission promulgated regulations requiring LNG applicants to use a pre-filing process for an application for authorization to construct or modify an LNG terminal.¹² Section 3(f) requires that the Commission obtain the concurrence of the Secretary of War before authorizing the siting, construction, expansion, or operation of LNG terminals affecting the

⁶ 15 U.S.C. 717b(a).

⁷ 15 U.S.C. 717b(e)(1). LNG terminal is defined as: “all natural gas facilities located onshore or in State waters that are used to receive, unload, load, store, transport, gasify, liquefy, or process natural gas that is imported to the United States . . . , exported to a foreign country . . . , or transported in interstate commerce by waterborne vessel, but does not include (A) waterborne vessels used to deliver natural gas to or from any such facility; or (B) any pipeline or storage facility subject to the jurisdiction of the Commission under [section 7].” *Id.* 717a(11). For purposes of this rulemaking an LNG terminal is a type of LNG plant.

⁸ *Id.* 717f(c)(1)(A).

⁹ *Id.* 717b(a), 717b(e)(3), 717f(e). For a discussion of the Commission’s authority to condition its approvals of LNG plants under section 3 of the NGA, see, e.g., *Distrigas Corp. v. FPC*, 495 F.2d 1057, 1063–64 (D.C. Cir. 1974), *cert. denied*, 419 U.S. 834 (1974); *Dynegy LNG Prod. Terminal, L.P.*, 97 FERC ¶ 61,231 (2001).

¹⁰ These requirements do not apply to NGA section 7 LNG plants, including LNG peak shaving facilities, which store gas in interstate commerce.

¹¹ 15 U.S.C. 717b–1(a).

¹² 18 CFR 157.21. Pre-filing is not required where the Director of the Office of Energy Projects (OEP) determines that prospective modifications to an existing LNG terminal do not involve significant state and local safety considerations that have not been previously addressed. *Id.* 157.21(a).

³ These facilities and some of their components are also described in FERC Office of Energy Projects, *Guidance Manual for Environmental Report Preparation for Applications Filed Under the Natural Gas Act*, Volume II (Feb. 2017), <https://www.ferc.gov/sites/default/files/2020-04/guidance-manual-volume-2.pdf>.

⁴ NGLs include ethane, propane, butane, isobutane, and pentanes.

⁵ Liquefaction facilities include refrigerant truck unloading, refrigerant storage containers, refrigerant transfer pumps, refrigeration compressors, air- or water-cooled heat exchangers to cool compressed refrigerants, refrigerant-cooled heat exchangers to cool natural gas to LNG, turboexpanders or hydraulic turbines, end flash gas vessels, and other components.

training or activities of an active military installation.¹³ Section 3A(e) states that “[i]n any order authorizing an LNG terminal the Commission shall require the LNG terminal operator to develop an Emergency Response Plan [that] shall be prepared in consultation with the United States Coast Guard and State and local agencies and be approved by the Commission prior to any final approval to begin construction [and] shall include a cost-sharing plan.”¹⁴ Additionally, section 3A(c) allows states to provide a report on state and local safety considerations, which “the Commission shall review and respond specifically to the issues raised”¹⁵

10. LNG operators may make modifications to already-approved, operating LNG plants during the life of the plant.¹⁶ To receive authorization for such modifications, the operator may need to file a case-specific application, which the Commission must evaluate, followed by a public interest determination.¹⁷

C. The Commission’s Existing Regulations for Authorizing Routine Pipeline Activities Under Section 7 Provide an Analogue for a Program for LNG Plants

11. Under Part 157, Subpart F of the Commission’s regulations,¹⁸ interstate pipelines that hold certificates of public convenience and necessity under NGA section 7 may apply for a blanket

certificate to undertake, without case-specific authorizations, certain activities automatically, subject only to annual reporting requirements,¹⁹ and certain other activities after prior notice.²⁰ Both sets of activities are subject to cost limits.²¹ The section 7 pipeline blanket certificate program “provide[s] streamlined procedures which increase flexibility and reduce regulatory burden” for a generic class of routine activities with particular conditions and procedures for consistency with the Commission’s statutory obligations under the NGA and environmental statutes.²²

12. In 1982, the Commission instituted this program, explaining that:

[T]he final regulations divide the various actions that the Commission certificates into several categories. The first category applies to certain activities performed by interstate pipelines that either have relatively little impact on ratepayers, or little effect on pipeline operations. This first category also includes minor investments in facilities which are so well understood as an established industry practice that little scrutiny is required to determine their compatibility with the public convenience and necessity. The second category of activities provides for a notice and protest procedure and comprises certain activities in which various interested parties might have a concern. In such cases there is a need to provide an opportunity for a greater degree of review and to provide for possible adjudication of controversial aspects. Activities not authorized under the blanket certificate are those activities which may have a major potential impact on ratepayers, or which propose such important considerations that close scrutiny and case-specific deliberation by the Commission is warranted prior to the issuance of a certificate.²³

13. The notice and protest procedures for prior notice projects allow anyone, including Commission staff, to protest a prior notice project within 60 days and, if a protest is not withdrawn or dismissed, the project is reviewed as an application for case-specific authorization under NGA section 7.²⁴

14. Section 7 pipeline blanket certificate activities are subject to the conditions in the Commission’s regulations implementing the National Environmental Policy Act (NEPA),²⁵ as well as requirements that all activities be consistent with applicable laws, including the Endangered Species Act (ESA), National Historic Preservation Act (NHPA), Clean Water Act (CWA), Clean Air Act, and other statutes relating to environmental concerns.²⁶

15. In addition to the section 7 pipeline blanket certificate program, § 2.55 of the Commission’s regulations allows interstate pipeline companies to perform auxiliary installations and facility replacements without a case-specific authorization.²⁷ For activities undertaken pursuant to either the blanket certificate program or § 2.55, section 7(c) certificate holders are required to provide advance notice to affected landowners.²⁸

16. In two earlier section 7 pipeline blanket certificate rulemakings, the Commission declined to extend the program to include LNG plants. In the 1982 rulemaking, the Commission excluded LNG plants from the program, finding that they “may have a significant impact on ratepayers” and therefore “should not be authorized under a blanket certificate, but should be subjected instead to the scrutiny of a case-specific determination.”²⁹ In 2006, the Commission again declined to extend the program to include LNG plants,³⁰ explaining that “LNG plant facilities are not within the class of minor, well-understood, routine activities that the blanket certificate program is intended to embrace; LNG plant facilities necessarily require a

¹³ 15 U.S.C. 717b(f). Pursuant to a Memorandum of Understanding (MOU) with the Department of War (DoW), the Commission issues a letter to the Department, which then responds indicating whether there are no or minimal impacts to military installations and operations. *Memorandum of Understanding Between the Federal Energy Regulatory Commission and the Department of Defense to Ensure Consultation and Coordination on the Effect of Liquefied Natural Gas Terminals on Active Military Installations* (Nov. 21, 2007, updated Aug. 29, 2014), <https://www.ferc.gov/media/2007-mou-dod>.

¹⁴ *Id.* 717b–1(e).

¹⁵ *Id.* 717b–1(c).

¹⁶ LNG projects occurring during operation may include, but are not limited to: safety system installations, existing equipment upgrades or replacements, emissions controls, system modifications to enable integration with non-jurisdictional activities (helium extraction or offsite carbon capture and sequestration), uprates, extra power generation, and new LNG trains, storage tanks, or loading berths. See, e.g., *Freeport LNG Dev., L.P.*, 175 FERC ¶ 61,237 (2021) (authorizing a non-jurisdictional helium extraction and purification plant); *Distigas of Mass. LLC*, 193 FERC ¶ 61,143 (2025) (authorizing the installation of a boil-off gas compressor); *Corpus Christi Liquefaction, LLC*, 195 FERC ¶ 61,161 (2026) (authorizing an uprate).

¹⁷ 18 CFR part 153 (detailing the requirements for applications filed pursuant to section 3 of the NGA); 18 CFR part 157 (detailing the requirements for applications filed pursuant to section 7 of the NGA).

¹⁸ 18 CFR part 157, subpart F.

¹⁹ *Id.* 157.203(b), 157.208(a), (e).

²⁰ *Id.* 157.203(c), 157.208(b).

²¹ *Id.* 157.208(d), 157.215(a)(5).

²² *Interstate Pipeline Certificates for Routine Transactions*, Order No. 234, FERC Stats. & Regs. ¶ 30,368, at 30,201 (1982) (cross-referenced at 19 FERC ¶ 61,216); see also *Revisions to the Blanket Certificate Regulations & Clarification Regarding Rates*, Order No. 686, 117 FERC ¶ 61,074, at P 7 (2006) (“The blanket certificate program was designed to provide an administratively efficient means to authorize a generic class of routine activities, without subjecting each minor project to a full, case-specific NGA section 7 certificate proceeding.”).

²³ Order No. 234, FERC Stats. & Regs. ¶ 30,368 at 30,200.

²⁴ 18 CFR 157.205(h).

²⁵ *Id.* part 380. Certain activities undertaken pursuant to the blanket certificate are categorically excluded from NEPA review. *Id.* 380.4(a)(21).

²⁶ *Id.* 157.206.

²⁷ *Id.* 2.55. LNG facilities authorized under section 7 of the NGA may use the procedures outlined in § 2.55.

²⁸ *Id.* 157.203(d)(1) (requiring affected landowners to be notified of automatic authorization projects at least 45 days prior to commencing construction or at the time it initiates easement negotiations, whichever is earlier); *id.* 157.203(d)(2) (requiring affected landowners to be notified of prior notice projects within three days following the date that a docket number is assigned to the application or at the time the certificate holder initiates easement negotiations, whichever is earlier); *id.* 2.55(c) (requiring a good faith effort to notify in writing each affected landowner at least five days prior to commencing any activity except for activities for which all ground disturbance will be within an existing above-ground site or those done for safety, US Department of Transportation (DOT) compliance, or environmental or unplanned maintenance reasons that are not foreseen and that require immediate attention).

²⁹ Order No. 234, FERC Stats. & Regs. ¶ 30,368 at 30,206.

³⁰ Order No. 686, 117 FERC ¶ 61,074 at PP 18–23.

review of engineering, environmental, safety, and security issues that the Commission believes only can be properly considered on a case-by-case basis.”³¹

17. The Commission’s experience with LNG plants has changed considerably since the 1982 and 2006 rulemakings. Specifically, both the Commission and the LNG industry have gained significant experience regarding the engineering, environmental, safety, and security issues at LNG plants. The Commission has evaluated more than 100 applications related to LNG plants since 2006. Staff has also engaged in extensive coordination with the DOT’s Pipeline and Hazardous Materials Safety Administration (PHMSA) and the US Coast Guard (USCG), which are involved in the safety and security of these facilities, as well as the LNG industry, to proactively develop safety and security standards and best practices.³²

18. Changes in the LNG market since 2006 have led to an expansion in the number of projects that the Commission regulates. The United States emerged as the world’s largest LNG exporter in

2023³³ with seven large-scale LNG export terminals currently in operation, eight new or expanded LNG export projects in construction, and additional LNG terminals and expansions expected over the next several years. Although certain changes and variances are permitted during the construction of an LNG plant, changes to an operating LNG plant—in some cases even routine adjustments like equipment replacements—may currently require case-specific authorization. The current case-by-case review process for certain replacements, modifications, and expansions is administratively inefficient and slows down the authorization of needed projects.

19. Based on these considerations, the Commission believes that the establishment of an LNG blanket program allowing the automatic or prior notice authorization for certain activities is warranted.

II. Notice of Inquiry

20. On November 20, 2025, the Commission issued a notice of inquiry (NOI) in this proceeding, requesting information and comments on whether and if so how to revise its regulations to allow for the authorization of activities at LNG plants without case-specific authorization under section 3 or 7 of the NGA.³⁴ The NOI was published in the **Federal Register** on November 25, 2025,³⁵ and established a 60-day comment period expiring on January 27, 2026.³⁶ In response to the NOI, the Commission received 18 comments—eight from LNG and natural gas companies and related trade associations,³⁷ one from an energy

technology company, two from engineering consulting firms, six from public interest organizations, and one on behalf of nine states’ attorneys general.³⁸ The comments addressed a variety of issues, including: support for a blanket program as it would allow certain activities at LNG plants to proceed in an expedited fashion; recommendations on how the Commission should implement a program with a tiered authorization system that would allow automatic approval for minor, in-footprint modifications and a prior notice process for moderate changes; recommendations that the LNG blanket program not include costs limits; questions pertaining to how the public and state agencies would receive notice; concerns about environmental effects and safety impacts; and questions as to whether the LNG industry is suitable for a blanket authorization program. The comments are addressed below.

III. Discussion

21. After reviewing the comments received in response to the NOI, the Commission proposes to establish an LNG blanket program to authorize certain activities at LNG plants without case-specific authorization orders under sections 3 and 7 of the NGA.

22. Specifically, the Commission proposes adopting a tiered blanket authorization program like the section 7 pipeline blanket certificate program, including activities that are eligible for automatic authorization or prior notice authorization. In general, activities that would not: (a) increase the authorized capacity of the LNG plant;³⁹ (b) expand the authorized vertical or horizontal extents within the footprint⁴⁰ of the LNG plant; or (c) result in flows, levels, volumes, pressures, temperatures, compositions, or loads outside any of the design limits of the new, replaced, or modified LNG facilities, auxiliary systems, and components and within the authorized design limits of the remaining LNG facilities, auxiliary systems, and components⁴¹ would be

³¹ *Id.* P 21 (quoting *Revisions to the Blanket Certificate Reguls. & Clarification Regarding Rates*, NOPR, 115 FERC ¶ 61,338, at PP 29–30 (2006)); see also *Revisions to the Blanket Certificate Regulations & Clarification Regarding Rates*, Order No. 686–A, 72 FR 37431 (July 10, 2007), 119 FERC ¶ 61,303, at P 22 (2007) (“[T]he blanket certificate program is not well suited to address the complexity inherent in issues raised by LNG . . . facilities”).

³² In individual proceedings, the Commission has issued over 4,500 requirements, including approximately 4,000 requirements that have been coordinated with PHMSA and the USCG regarding the engineering, safety, security, and reliability of those projects in accordance with a 2004 Interagency Agreement. *Interagency Agreement Among the Federal Energy Regulatory Commission, United States Coast Guard, and Research and Special Programs Administration for the Safety and Security Review of Waterfront Import/Export Liquefied Natural Gas Facilities* (Feb. 11, 2004), <https://www.ferc.gov/media/2004-interagency-dot-and-uscg>. Approximately 30 of these orders were issued after a 2018 MOU with DOT for coordination between the Commission and PHMSA on determining whether proposed LNG facilities comply with PHMSA’s siting requirements contained in 49 CFR part 193, subpart B. *Id.*; see also *Memorandum of Understanding Between the Department of Transportation and the Federal Energy Regulatory Commission Regarding Liquefied Natural Gas Transportation Facilities* (Aug. 31, 2018), <https://cms.ferc.gov/media/mou-phmsa-regarding-lng-transportation-facilities-0>. Commission staff, along with DOT PHMSA and USCG representatives, have also actively participated in an LNG Technical Committee, and Commission staff has made over 300 proposals since 2016 to update subsequent versions of the National Fire Protection Association (NFPA) 59A, *Standard for the Production, Storage, and Handling of LNG*, to improve the safety, security, and reliability of LNG projects consistent with the requirements that the Commission imposes on LNG facilities in its authorization orders.

³³ US Energy Info. Admin., *The United States Was the World’s Largest Liquefied Natural Gas Exporter in 2023* (Apr. 1, 2024), <https://www.eia.gov/todayinenergy/detail.php?id=67864>; see also US Energy Info. Admin., *Global Liquefied Natural Gas Trade Volumes Reached Record High in 2025* (July 14, 2026), <https://www.eia.gov/todayinenergy/detail.php?id=67864>; US Dep’t of Energy, Office of Fossil Energy & Carbon Mgmt., *Liquefied Natural Gas (LNG) Exports* (Dec. 31, 2025), https://www.energy.gov/sites/default/files/2025-12/LNG%20Snapshot%20Dec%2031%202025_0.pdf.

³⁴ *Authorizations for Certain Activities at Liquefied Nat. Gas Plants*, 193 FERC ¶ 61,141 (2025) (NOI).

³⁵ 90 FR 53251 (Nov. 25, 2025).

³⁶ 18 CFR 385.2007(a)(2) (the last day of time period does not end until the close of the Commission business of the next day which is not a day on which the Commission closes due to adverse conditions).

³⁷ Cheniere Energy, Inc. (Cheniere), Interstate Natural Gas Association of America (INGAA), Natural Gas Supply Association (NGSA), and Rio Grande LNG, LLC, filed comments in support of Center for LNG’s (CLNG) proposal for a section 3 blanket authorization. Where entities filed comments in support of a particular proposal offered by CLNG, that is noted below, but similar arguments are not repeated.

³⁸ The Commission also received motions to intervene from Atmos Energy Corp., Symmetry Energy Solutions, and the Maryland Office of the Attorney General.

³⁹ *Capacity* would be defined at § 153.102(a)(8) as the (i) import or export capacity of the LNG terminal or (ii) storage and delivery capacity of the interstate LNG plant.

⁴⁰ *Footprint* would be defined at § 153.102(a)(9) to mean the area located (i) within an LNG plant’s security systems; and (ii) within the areas protected from natural hazards.

⁴¹ *Design limits* would be defined at § 153.102(a)(10) as the (i) minimum and maximum design flows; (ii) minimum and maximum liquid design levels and volumes; (iii) minimum (vacuum)

eligible for automatic authorization.⁴² Activities that would increase the authorized capacity of the LNG plant, be located within the footprint of the LNG plant, not result in any change in flows, levels, volumes, pressures, temperatures, compositions, or loads outside the design limits of the new, replaced and modified LNG facilities, auxiliary systems, and components, and not result in any aforementioned changes outside the authorized design limits of the remaining LNG facilities, auxiliary systems, and components, would be subject to a 60-day prior notice period. Construction of new LNG facilities, such as liquefaction trains, LNG tanks, and marine berths, and auxiliary systems outside of the footprint of the plant would be subject to a 90-day prior notice period.

23. The Commission also proposes standard environmental and engineering design conditions to address the impacts of blanket projects as well as requirements to ensure compliance with applicable law. To the extent practicable, the proposed LNG blanket program is modeled after the pipeline blanket program. But unlike the pipeline blanket program, LNG blanket projects would not be subject to cost limits because in the Commission's experience the cost of LNG activities does not serve as an appropriate proxy to determine whether those activities should be eligible for the blanket authorization program. Moreover, LNG terminals authorized under section 3 of the NGA do not implicate the same ratepayer concerns because the Commission does not regulate rates under NGA section 3.⁴³ Rather, the Department of Energy (DOE) evaluates the economic impact of a proposal to export natural gas as part of its decision whether to authorize the export of natural gas, as a commodity,⁴⁴ to non-Free Trade Agreement countries.⁴⁵

and maximum design pressures; (iv) minimum design metal temperature and maximum design temperature; (v) minimum and maximum compositions; and (vi) maximum structural design loads and criteria.

⁴² The authorized capacity and design limits include those approved by staff under delegated authorities.

⁴³ With respect to section 7 LNG plants, as described below in section III.B.5, the Commission proposes to impose the same rate requirements as under the blanket certificate program.

⁴⁴ The Commission does not authorize importation or exportation of the commodity itself. Rather, an application for authorization to import or export natural gas must be submitted to the DOE. 15 U.S.C. 717b(a).

⁴⁵ Under section 3(c) of the NGA, the exportation of natural gas to a Free Trade Agreement country is deemed to be consistent with the public interest. 15 U.S.C. 717b(c).

A. Applicability to Section 7 LNG Plants

24. As detailed above in section I.B, section 3 and section 7 LNG plants share some characteristics; however, their statutory and regulatory structure is different, as are the facilities that are constructed and operated under sections 3 and 7, respectively.

25. In the NOI, the Commission sought comment on whether modifications to section 7 LNG plants should be included under the blanket program.⁴⁶ The NOI also requested comment on whether cost-based limits would be appropriate for such projects.⁴⁷

26. Commenters support the expansion of the Part 157 blanket program to include LNG facilities in interstate commerce.⁴⁸ Eastern Shore Natural Gas Company (Eastern Shore)⁴⁹ states that small LNG storage facilities would benefit from blanket authority to conduct routine modifications and improvements.⁵⁰

27. We propose that section 7 LNG plants be eligible for the blanket authorization program, and that the eligible activities be the same as under the section 3 blanket program, albeit with some additional requirements detailed below.

B. Eligible Facilities

28. The NOI sought comment on whether to adopt a tiered approach to the proposed LNG blanket authorization program under which certain activities are automatically authorized and other activities are authorized after prior notice, and if so how the Commission should define the activities and establish tiers for them.⁵¹

29. Generally, in response to the NOI, commenters propose a structure similar to the Commission's section 7 pipeline blanket program, where certain categories of actions would be eligible for automatic authorization and a larger, more complex group of actions would be eligible for prior notice authorization. CLNG,⁵² American Petroleum

Institute,⁵³ and INGAA⁵⁴ (collectively, CLNG) propose that the Commission adopt a three-tiered approach which includes: automatic authorizations; standard prior notice authorization for facility modifications that would not result in changes to hazards or public safety; and an expanded prior notice for larger activities like new liquefaction trains, storage tanks, or marine berths.⁵⁵ CLNG requests that the Commission continue to allow some modifications at operational LNG terminals through disclosure in semi-annual operational reports and management of change (MOC) logs (together, Change Reporting Process).⁵⁶ Each order authorizing an LNG plant contains requirements for the authorization or certificate holder to file a semi-annual operational report listing modifications undertaken at the LNG plant and any significant modifications proposed for the next 12 months.⁵⁷ These reports provide early notice to staff of anticipated future construction and maintenance and allow staff to advise LNG companies on whether such modifications require a separate amendment application. Authorizations also include a condition that allows Commission staff to inspect LNG facilities and issue data requests to LNG companies throughout the life of the facilities. Under those delegated powers, Commission staff request MOC logs to verify that modifications undertaken at LNG terminals and plants are consistent with the semi-annual operational reports and that there are no safety or reliability impacts from those changes. CLNG notes, however, that the existing Change Reporting Process lacks clarity, creating "regulatory inconsistencies, inefficiency, and . . . potential non-compliance risk."⁵⁸

30. Earthjustice⁵⁹ and the Attorneys General for the States of Maryland, Oregon, Connecticut, Delaware, Massachusetts, Michigan, New York, Rhode Island, and Vermont (collectively, States) oppose allowing expansions of new or existing LNG terminals or facilities under a blanket

⁴⁶ NOI, 193 FERC ¶ 61,141 at P 13, Question B6.

⁴⁷ *Id.* P 13, Question B7.

⁴⁸ See BLUE January 23, 2026 Comments at 3, 7–8.

⁴⁹ Eastern Shore is the certificate holder for the Worcester Resiliency Upgrade, which is under construction and includes an LNG storage facility in Bishopville, Maryland.

⁵⁰ Eastern Shore January 26, 2026 Comments at 2–3.

⁵¹ NOI, 193 FERC ¶ 61,141 at P 13, Questions A3, B1–B4.

⁵² The Center for Liquefied Natural Gas is a trade association that promotes public policies advancing the use of natural gas in the United States and its export internationally.

⁵³ The American Petroleum Institute is a nationwide, non-profit trade association that represents all facets of the natural gas and oil industry.

⁵⁴ INGAA is a trade association that advocates regulatory and legislative positions of importance to the interstate natural gas pipeline industry in the United States.

⁵⁵ CLNG January 26, 2026 Comments at 10–11.

⁵⁶ *Id.* at 4 n.7, 10–11.

⁵⁷ See, e.g., *Corpus Christi Liquefaction, LLC*, 190 FERC ¶ 61,149, at app. A, env't condition 100 (2025).

⁵⁸ *Id.* at 8.

⁵⁹ Earthjustice is a nonprofit public interest environmental law organization.

program.⁶⁰ The States assert that this would infringe upon the state and local interests protected by the NGA.⁶¹

31. Our proposal here, consistent with the structure and rationale of the longstanding section 7 pipeline blanket program, would streamline the review of LNG authorization requests to increase flexibility and reduce regulatory burden through the establishment of an LNG blanket program.⁶² In other words, the blanket program, coupled with the existing authorization process, would provide blanket authorization holders with procedural mechanisms for authorization of facilities that are commensurate with the degree of associated effects (*i.e.*, a range from automatic authorization through prior notice to a full authorization application) while continuing to fully consider state and local interests.

32. Below we detail the proposed LNG blanket program, which would establish a tiered approach for blanket-eligible activities. This would include a category of actions eligible for automatic authorization and a category of actions that would be eligible following prior notice procedures. Under the prior notice procedures, the Commission would issue notice of the proposed activity and interested stakeholders, as well as Commission staff, would have an opportunity to protest. If a protest is filed and not withdrawn or dismissed, the project would be reviewed as an application for case-specific authorization under the NGA; otherwise, the project could proceed at the end of the notice period.

1. Automatic Authorization

33. The NOI sought comment on what types of activities the Commission should find eligible for automatic authorization procedures.⁶³

34. CLNG commented that the automatic authorization tier should cover modifications, additions, or improvements to LNG plants that extend beyond the routine activities covered by the Change Reporting Process (which CLNG advocates that the Commission maintain after the LNG blanket program is authorized), but that do not involve any changes to overall design, new offsite thermal radiation or flammable vapor impacts, increases in permitted noise levels, new types of pollutants or hazards, or new landowner

or public use impacts.⁶⁴ Under CLNG's proposal, automatic authorization could allow for increases in capacity through uprates if the uprate is based upon efficiencies realized after the original authorization.

35. Specifically, CLNG's proposed automatic authorization tier would require: (i) the proposed activity be within the existing LNG plant footprint or located on adjacent or nearby land that is currently owned or controlled by the blanket authorization holder; (ii) no effects to sensitive environmental resources outside the original scope of the NEPA review of the plant; (iii) all construction or modifications comply with the conditions and environmental mitigation methods from the original section 3 authorization order; (iv) no increase to the authorized annual total LNG production or storage capacity that exceeds the design limits of existing systems and equipment; and (v) continued compliance with USCG, PHMSA, and other permitting agency regulations.⁶⁵

36. CLNG provides the following examples of automatic authorization activities: (i) equipment uprates or rearrangements that improve efficiency, safety, capacity, emissions, or reliability; (ii) installation of additional safety systems or emission control devices; (iii) installation of auxiliary systems; (iv) replacements and upgrades of infrastructure that are not an in-kind replacement but result in no greater hazard footprint or environmental impacts; (v) installation of addition of instrumentation, monitoring systems, or controls; (vi) installation of new or improved components that do not introduce new unmitigated hazards; (vii) uprating of capacities through activities such as debottlenecking, optimizing existing trains, or implementing improvements during construction; (viii) installation of redundant components that introduce no new unmitigated hazards; (ix) installation of components required to operate within the authorized facility design limits; (x) installation of new or additional truck loading facilities for non-hazardous material transport; and (xi) activities required for maintaining compliance with regulations, regardless of the complexity of the project.⁶⁶

37. CLNG and Cheniere⁶⁷ maintain that many optimizations and in-kind

modifications that are performed within the existing footprint—such as replacing older equipment with newer, safer models, installing advanced leak detection systems, upgrading fire and gas detection systems, debottlenecking activities, or installing pollution control devices or emissions monitoring devices—would result in no adverse environmental impacts and would yield reliability and safety benefits.⁶⁸

38. The Center for Regulatory Freedom⁶⁹ proposes that the automatic authorization tier include low-impact and routine activities such as equipment replacements, maintenance actions, safety system upgrades, and efficiency improvements.⁷⁰

39. Blue Engineering and Consulting Company (BLUE)⁷¹ recommends that the automatic authorization tier include modifications focused on operations, maintenance, safety, reliability, and efficiency improvements that would result in no impacts to the public or the environment.⁷² It provides the following examples of modifications: (i) debottlenecking activities to improve efficiency and increase throughput; (ii) installation of redundant equipment to increase reliability and minimize downtime; (iii) installation of nitrogen rejection units, helium removal, component injection into feed gas streams, or other removal/injection to handle changes in feed gas composition; (iv) installation or modification of pretreatment technologies to account for feed gas changes; and (v) modification of technologies to meet permit requirements, account for changes in feed gas composition, or account for operational changes.

40. Woodside Energy (USA) Inc. (Woodside)⁷³ supports automatic authorizations for activities that do not materially expand or alter the facility's previously authorized environmental footprint or LNG capacity.⁷⁴

northern shore of Corpus Christi Bay in San Patricio and Nueces Counties, Texas, respectively.

⁶⁸ CLNG January 26, 2026 Comments at 28, 32; Cheniere January 26, 2026 Comments at 5–6.

⁶⁹ The Center for Regulatory Freedom is a project of the Conservative Political Action Coalition Foundation, a non-profit, non-partisan 501(c)(3) research and education foundation.

⁷⁰ Center for Regulatory Freedom Comments at 9.

⁷¹ BLUE is an engineering and consulting firm which provides regulatory services to various LNG facilities during the permitting, construction, commissioning, and in-service phases.

⁷² BLUE January 23, 2026 Comments at 4.

⁷³ Woodside is the owner of Woodside Louisiana LNG, formerly the Driftwood LNG project, which is under construction near the city of Carlyss in Calcasieu Parish, Louisiana.

⁷⁴ As examples of projects that it proposes should fall under an automatic authorization, Woodside suggests rearrangements or replacements of piping.

Continued

⁶⁰ States Comments at 11; Earthjustice January 26, 2026 Comments at 3.

⁶¹ States Comments at 11–12.

⁶² Order No. 234, FERC Stats. & Regs. ¶ 30,368 at 30,200–01.

⁶³ NOI, 193 FERC ¶ 61,141 at P 13, Question B1.

⁶⁴ CLNG January 26, 2026 Comments at 11–13.

⁶⁵ *Id.* at 14.

⁶⁶ *Id.* at 12–13.

⁶⁷ Cheniere, through its subsidiaries, is the owner of the Sabine Pass LNG Terminal and Corpus Christi LNG Terminal located near the Sabine Pass Channel, Cameron Parish, Louisiana, and on the

EcoEléctrica, L.P. (EcoEléctrica),⁷⁵ supports allowing automatic authorization for modifications related to operations, maintenance, safety, reliability, and efficiency improvements that result in no impacts to the public or the environment.⁷⁶

41. As the Commission explained in its section 7 pipeline blanket certificate proceeding, activities eligible for automatic authorization are “so well understood as an established industry practice that little scrutiny is required to determine their compatibility with the public convenience and necessity.”⁷⁷ Here, we agree with commenters that certain activities at LNG plants are so well understood they would similarly require little scrutiny to determine that they are not inconsistent with the public interest, as required by section 3, or are in the public convenience and necessity, as required by section 7.

42. The automatic authorization category would establish a regulatory path for efficient implementation of modifications at existing LNG plants without unnecessary regulatory burdens, while maintaining compliance with both the NGA and NEPA. The proposed automatic authorization category is limited to facilities that (1) do not result in expansions or increases of the authorized capacity of the LNG plant, (2) are within the existing horizontal and vertical extents of the footprint and design limits,⁷⁸ (3) do not result in adverse safety or reliability impacts at the plant, and (4) would have only minor or no environmental effects.

43. We propose at § 153.108 and § 153.109 to include the following activities under the automatic authorization category:

Abandonment

Abandonment of any components, systems, or facilities that do not impact existing customers under contract and do not adversely affect the continued safety, reliability, or environmental protection of operational facilities.

equipment replacements, and improvements to support infrastructure such as electric and water distribution. Woodside January 26, 2026 Comments at 2.

⁷⁵ EcoEléctrica is the owner and operator of EcoEléctrica LNG at Guayanilla Bay, Peñuelas, about nine miles west of Ponce, Puerto Rico.

⁷⁶ EcoEléctrica Comments at 1.

⁷⁷ Order No. 234, FERC Stats. & Regs. ¶ 30,368 at 30,200.

⁷⁸ Changes shall not result in flows, levels, volumes, pressures, temperatures, compositions, or loads outside any of the design limits of the new, replaced, or modified LNG facilities, auxiliary systems, and components and the authorized design limits for the remaining LNG facilities, auxiliary systems, and components.

Components Within LNG Facilities

For the components listed below,⁷⁹ replacements (in-kind or upgraded⁸⁰) including the abandonment of existing equipment, modifications,⁸¹ or new components at authorized LNG facilities that do not increase the authorized capacity of the LNG terminal or plant and within the authorized vertical and horizontal extents of the footprint and design limits of the LNG plant facilities and auxiliary systems:

- (a) piping and valves;
- (b) process vessels;
- (c) storage containers;
- (d) rotating equipment;
- (e) fired equipment;
- (f) instrumentation and control system components;
- (g) safety instrumented system components;
- (h) buildings and structures; and
- (i) electrical components.

Auxiliary Systems

Replacements (in-kind or upgraded) including the abandonment of existing equipment, modifications, or additions of the following components or systems to maintain or improve the safety and reliability of operations of LNG facilities and that do not increase the authorized capacity of the LNG terminal or plant and within the authorized vertical and horizontal extents of the footprint and design limits of the LNG facilities and auxiliary systems:

- (a) vapor handling systems;
- (b) fuel gas systems;
- (c) nitrogen and inert gas systems;
- (d) instrument, plant/utility air systems;
- (e) utility water and other utility systems;
- (f) power generation and electrical systems;
- (g) emission control systems;
- (h) cathodic protection systems;
- (i) security systems;
- (j) relief valve and flare/vent systems;
- (k) spill containment systems;
- (l) passive protection systems;
- (m) hazard detection systems;
- (n) hazard control systems;
- (o) firewater systems;
- (p) structural systems;
- (q) natural hazard mitigation systems; and
- (r) emergency response systems.

Related Pipeline Facilities

Construction of pipeline facilities under section 3 of the NGA to the same extent as is allowed under the section 7 pipeline blanket certificate program.

⁷⁹ We propose to define individual components in § 153.102.

⁸⁰ Upgraded would be defined in § 153.102(a)(13) as providing equal or greater level of safety, security, reliability, operability, efficiency, and environmental protection.

⁸¹ Modify would be defined in § 153.102(a)(14) as changes to the siting, design, construction, or operational conditions of components within authorized LNG facilities and auxiliary systems, including but not limited to changes in process controls, software, setpoints, size/diameter, wall thickness, materials of construction, routing, location, or other process, mechanical, electrical, hazard mitigation, or structural related specifications, designs, or operations.

44. Activities that would not be eligible for automatic authorization include increases in capacities of the LNG terminal or plant and projects that would extend beyond the existing LNG plant footprint because these activities have the potential for safety and environmental impacts and thus are better suited for the prior notice category of actions.

45. Further, we do not propose to allow increases of the authorized capacity through uprates under automatic authorization, even where efficiencies are realized during construction, because such increases may implicate hazards, safety concerns, and environmental effects associated with increased throughput. Such issues historically have been addressed through safety and environmental reviews prior to start-up. Moreover, the changes vary from plant to plant and may result in more or larger LNG marine vessels, requiring a more detailed analysis by Commission staff or its federal agency partners. Further, these changes could also require a new letter of recommendation from USCG; a letter of determination from PHMSA; concurrence from the DoW; the opportunity for state agencies to submit a state safety advisory report; updated Emergency Response Plans developed in consultation with USCG and state and local agencies; and ESA consultation. Therefore, such uprates would be eligible under prior notice procedures.

46. As for CLNG's proposal that the existing Change Reporting Process⁸² be preserved as a means to modify LNG plants separate from the blanket program, we disagree. The existing Change Reporting Process does not provide a clear, consistent, and certain regulatory path for modifying LNG plants.⁸³ Conversely, the proposed blanket program will provide a path for routine, well understood repairs, replacements, and additions at LNG plants to receive regulatory approval with a shorter time frame, compared with traditional case-specific authorizations. The automatic authorization activities would include those intended to be covered by the semi-annual operational reports and the prior notice procedures would establish a separate streamlined authorization process to provide more consistency and regulatory certainty for those

⁸² See *supra* P 29 (“Change Reporting Process” is the term used by CLNG to cover modifications made at LNG terminals through both the semi-annual reporting and the MOC processes).

⁸³ See CLNG January 26, 2026 Comments at 8 (recognizing that the Change Reporting Process lacks clarity).

activities while balancing the potential impacts of those activities. Nevertheless, as described below in section III.C.7, the semi-annual reporting requirements would be maintained and would continue to keep staff apprised of planned changes at each LNG plant.

2. Prior Notice

47. The NOI sought comment on what types of activities the Commission should find eligible for prior notice procedures.⁸⁴

48. CLNG proposes that prior notice projects be divided into two tiers. The first tier of prior notice projects would entail “facility modifications short of a new liquefaction train, LNG storage tank, or loading berth.”⁸⁵ CLNG’s proposal would allow increases in LNG production or feed gas throughput that may have offsite impacts or implicate other potential issues (e.g., safety modeling, effects on landowners, environmental impacts, etc.), but would remain within the scope and magnitude of the impacts already reviewed and approved as part of the terminal’s original authorization. For this tier, CLNG proposed a 30-day notice period.⁸⁶

49. Examples of the types of projects CLNG proposes to include in its first prior notice tier include: (i) LNG production increases beyond the previously authorized limit; (ii) adding a new process unit, system, or equipment to improve functionality or emissions but that does not expand storage; (iii) limited construction such as adding an extra power generator or a new control room that is consistent with previously assessed land use; (iv) modifications to the jurisdictional portions of an LNG terminal to enable integration with a complementary non-jurisdictional activity; (v) installation of new units or components as replacements of existing units or components with substantially equivalent design delivery capacity; and (vi) activities required for maintaining compliance with regulations, regardless of the complexity of the project, that otherwise do not meet the criteria for automatic authorization.⁸⁷

50. CLNG proposes that this tier include activities that increase LNG production or throughput capacity without the construction of new liquefaction trains, storage tanks, or LNG loading berths provided that: (i) any environmental effects must have been analyzed within the previous

NEPA analysis or will be addressed in a new NEPA analysis by another agency and the blanket authorization holder will obtain all required permits prior to commencement of construction; (ii) the project either does not require new land beyond the existing site or right-of-way or any new land is already under control of the blanket authorization holder; (iii) the project does not impact traffic and thermal radiation zones such that adjacent parcels not previously impacted would now be impacted; (iv) the project continues to comply with USCG, PHMSA, and other agency permits and requirements; and (v) preliminary noise modeling shows no exceedance of a day-night level (L_{dn}) of 55 dBA at the nearest noise sensitive area and a noise survey will be filed no later than 60 days after the in-service date.⁸⁸

51. In its second prior notice tier, CLNG proposes to allow the construction of new liquefaction trains, storage tanks, and LNG loading berths.⁸⁹ Specifically, CLNG proposes that obtaining prior notice authorization for new trains, storage tanks, and berths would require: (i) that the design of the proposed facility be based on an existing design of the blanket authorization holder or its affiliate, as modified to account for site-specific conditions, new models of equipment, safety, efficiency, and maintenance improvements, integration with existing facilities at the LNG plant, and any updates in applicable Federal regulations; (ii) continued compliance with all conditions present in the underlying section 3 authorization order except any changes necessary due to changed regulations; (iii) that any new site-specific environmental impacts be of the same kind as those reviewed in the underlying NEPA analysis or be covered in a new NEPA analysis prepared by another agency; (iv) that new waterway suitability assessments or environmental permits be obtained if needed; (v) that any changes to the plant’s existing safety design criteria are within the assumptions of prior models or else do not result in any parcels being included within the impact zones; (vi) that construction on new land adjacent or near the existing site will not significantly impact traffic; and (vii) that preliminary noise modeling shows no exceedance of an L_{dn} of 55 dBA at the nearest noise sensitive area and a noise survey must be filed within 60 days of

the in-service date.⁹⁰ CLNG states that all of its proposed prior notice activities would either replicate the design of existing facilities that were previously subject to NEPA review or that would be *de minimis* or not have significant impacts.⁹¹ For this tier of activities, CLNG proposes a notice period of 60 days.⁹²

52. In addition to the activities proposed by other commenters, Woodside proposes that dredging or marine adjustment within existing operational limits be allowed under a prior notice tier.⁹³

53. As the Commission explained in the 1982 section 7 pipeline blanket rulemaking, the prior notice tier of activities “provides for a notice and protest procedure and comprises certain activities in which various interested parties might have a concern,” such that “there is a need to provide an opportunity for a greater degree of review and to provide for possible adjudication of controversial aspects.”⁹⁴ We propose to establish a category of actions that would be eligible for prior notice authorization, which we have subdivided into two subcategories, one with a 60-day notice period and the other with a 90-day notice period, based on the Commission’s experience reviewing both initial requests for authorization and requests for modifications during construction, commissioning, and operation of LNG plants. Our proposed notice periods differ from CLNG’s and BLUE’s, but we believe the additional time—30 additional days for each prior notice category, as compared to CLNG’s proposal—is needed to enable the Commission, its staff, the public, affected landowners, and other interested parties sufficient time to review the proposals. Protest procedures for the blanket authorization program are discussed below, in section III.C.4.

54. We propose at § 153.108(d)(1) to make the following activities eligible under prior notice procedures with a 60-day notice period:

Components Within LNG Facilities

Replacements, including the abandonment of existing components; upgrades; and modifications of existing components or the addition of new components designed to increase the authorized capacity of the LNG terminal or plant and that are within the authorized footprint and design limits.

⁸⁴ NOI, 193 FERC ¶ 61,141 at P 13, Question B1.

⁸⁵ CLNG January 26, 2026 Comments at 10.

⁸⁶ *Id.* at 17.

⁸⁷ *Id.* at 15–16.

⁸⁸ *Id.* at 16.

⁸⁹ *Id.* at 18. BLUE proposes essentially the same activities for 60-day prior notice authorization as CLNG. BLUE January 23, 2026 Comments at 5–6.

⁹⁰ CLNG January 26, 2026 Comments at 18–19.

⁹¹ *See id.* at 11.

⁹² *Id.* at 19.

⁹³ Staff notes that the US Army Corps of Engineers, not the Commission, has jurisdiction over dredging.

⁹⁴ Order No. 234, FERC Stats. & Regs. ¶ 30,368 at 30,200.

Auxiliary Systems

Replacements, including the abandonment of existing components; modifications; or new auxiliary components and systems associated with existing LNG facilities designed to increase the authorized capacity of the LNG terminal or plant and that are within the authorized footprint and design limits.

Related Pipeline Facilities

Construction of pipeline facilities under section 3 of the NGA to the same extent as is allowed under the section 7 pipeline blanket certificate program.

55. We propose at § 153.108(d)(2) to make the following activities eligible under prior notice procedures with a 90-day notice period:

New LNG Facilities and Auxiliary Systems

New LNG facilities and auxiliary systems that would be constructed outside the authorized footprint.

56. Any projects undertaken under the 90-day prior notice category would be subject to the following conditions: (i) any expansion of facilities must be either within the existing LNG plant footprint or adjacent to the LNG plant and permanently occupy no more than 25 acres, occupy only previously-disturbed or developed land or waterways, and be within industrial zoned areas or areas without zoning; (ii) requests must demonstrate that any modifications outside the existing footprint will comply with all environmental and engineering conditions of the authorization for the plant; and (iii) the facilities must be of the same type (in-kind or upgraded) as those previously authorized by the Commission at the same LNG plant or terminal or reviewed and approved by Commission staff for the underlying authorization. We propose limiting the facility type to ensure sufficient time to analyze, within the limited timeframes contemplated under the proposed prior notice regulations, projects' potential hazards and safety and environmental impacts in light of the site-specific siting, design, construction, and operation of the LNG facilities in question. Further, § 153.108(f)(1) of the Commission's proposed regulations, which staff will enforce, prohibit blanket authorization holders from segmenting, separating, or dividing projects in order to meet the acreage limitation.

3. Blanket Activities Outside of the LNG Plant Footprint

57. The NOI sought comment on whether the Commission should allow the construction and operation of

facilities outside of the footprint of the currently authorized LNG plant.⁹⁵

58. Some commenters support allowing projects to occur both within and outside of the existing project footprint.⁹⁶ CH-IV International, LLC (CH-IV),⁹⁷ however, opposes allowing construction and operation of facilities outside of the plant limits but does not explain why.⁹⁸

59. As stated above, we propose to allow for the construction and operation of facilities outside of the LNG plant footprint. However, such facilities would be limited to a 25-acre area and would only be eligible for construction under the 90-day prior notice procedures.

60. We believe it would be unwise to limit expansions to those within the existing footprint. First, we understand, based on the experience of Commission staff, that an appropriately limited category of actions outside LNG plants' existing footprints can be fully and appropriately assessed through the proposed prior notice procedures. In particular, the engineering and environmental conditions (e.g., requiring that the new facilities be of the same type (in-kind or upgraded) as those previously authorized by the Commission at the same LNG plant or terminal) and the limitation on the location and size of the expansion permanently occupying no more than 25 acres on adjacent land help ensure that such projects will not have a significant impact on public safety or the environment. The prior notice procedures also allow for interested stakeholders to have an opportunity to evaluate proposals and raise particular concerns regarding a project's impact. Moreover, limiting blanket-eligible expansions to those within a plant's existing footprint could incentivize artificially congested development, resulting in potential safety concerns due to equipment congestion, which can create new hazards for and from maintenance activities, increase consequences from hazards, and impede emergency access and egress. Therefore, we find that such projects may qualify for the faster and more streamlined blanket procedures, so as to facilitate and expedite important infrastructure development without significant adverse impacts on public safety or the environment.

⁹⁵ NOI, 193 FERC ¶ 61,141 at P 13, Question B4.

⁹⁶ E.g., CLNG January 26, 2026 Comments at 14; Cheniere January 26, 2026 Comments at 6.

⁹⁷ CH-IV is a global engineering and consulting firm serving asset developers, regulators, owners, operators, and lenders across the energy, infrastructure, and resources industries.

⁹⁸ CH-IV January 16, 2026 Comments at 6.

61. Regarding the proposed 25-acre limit on blanket-eligible expansions outside a plant's existing footprint, Commission staff evaluated prior authorizations to determine what acreage would allow an LNG blanket authorization holder to construct new facilities of an appropriate scope for eligibility under the proposed 90-day prior notice tier. Staff determined that 25 acres would allow for the construction of two LNG tanks, a single large liquefaction train (e.g., 7.8 MTPA (1.08 Bcfd)), approximately 10 smaller liquefaction blocks (e.g., 20 liquefaction units totaling 12.5 MTPA (1.73 Bcfd)), or five combined-cycle power generation facilities. Staff determined based on its experience that the safety and environmental effects of such projects would be less than significant based on prior examples.⁹⁹ We emphasize that this analysis does not alter or diminish an applicant's obligation to comply with the requirements set forth in § 153.108(e)(4). In addition, the proposed regulations include general, environmental, and engineering conditions and criteria as delineated in §§ 153.106 and 153.108 to limit the impacts. However, we seek comment on:

- Whether 25 acres beyond the existing plant footprint is an appropriate acreage limitation?
- Whether the Commission should consider any additional limits or criteria for blanket eligibility for projects that extend beyond the existing plant footprint?

62. In addition, we propose to allow certain pipeline tie-in facilities to be constructed outside the existing plant footprint. These facilities would allow LNG blanket authorization holders to interconnect with pipeline systems without case-specific authorization.

⁹⁹ For example, in *Corpus Christi Liquefaction, LLC*, 190 FERC ¶ 61,149, the Commission authorized the construction and operation of the CCL Midscale Trains 8 & 9 Project, two midscale trains that would permanently occupy approximately 40 acres (i.e., each train would occupy 20 acres) and that the proposed project "would not constitute a major federal action significantly affecting the quality of the human environment." *Id.* P 130. Similarly, in *Port Arthur LNG Phase II*, 184 FERC ¶ 61,184 (2023), the Commission authorized the construction and operation of the Port Arthur LNG Expansion Project, two large scale liquefaction trains that would permanently occupy approximately 60 acres (i.e., each train occupied 30 acres) and found that the proposed project "would not constitute a major federal action significantly affecting the quality of the human environment." *Id.* P 130. See also *Sabine Pass Liquefaction Expansion, LLC*, 151 FERC ¶ 61,012, at P 122 (2015) (finding that the construction and operation of two liquefaction trains and other facilities would not constitute a major federal action significantly affecting the quality of the human environment).

Such facilities are well understood because many similar facilities have been constructed under the Commission's section 7 pipeline blanket program.¹⁰⁰

4. Cost Limits for LNG Facilities and Auxiliary Systems

63. The NOI sought comment on whether the Commission should use cost limits as a proxy to determine what activities are eligible under the proposed LNG blanket program.¹⁰¹

64. Under the section 7 pipeline blanket certificate regulations, activities are limited based on the cost of the proposed project.¹⁰² Several commenters oppose cost limits for the construction and operation of LNG facilities under an LNG blanket program because of the high variability in equipment cost and supply chain factors.¹⁰³ States comment that cost limits are not an appropriate surrogate for determining whether a project should be eligible for automatic or prior notice authorization because the Commission has not shown LNG facility projects and activities to be routine or generic.¹⁰⁴

65. We do not propose to include cost limits as part of the LNG blanket program for LNG plants. The costs associated with LNG and auxiliary systems do not serve as a reasonable proxy for their associated effects. Instead, the classifications we have proposed, which are based on the physical and operational nature of the activities at issue, provide a more appropriate proxy for the covered projects' expected environmental, safety, and hazard effects, and hence a better criterion for eligibility under the blanket program. Moreover, the Commission does not regulate rates under NGA section 3 as it does under section 7, so concerns about effects on ratepayers—one of the primary reasons for the section 7 cost limits—are not implicated.¹⁰⁵

5. Rate Treatment of Section 7 LNG Activities

66. The NOI sought comment on whether the Commission should treat section 7 LNG plants different from other interstate natural gas facilities.¹⁰⁶

67. Eastern Shore comments that the Commission should not place cost-based limits on section 7 LNG facilities as long as required environmental and landowner impact conditions are satisfied.¹⁰⁷ Given its experience, Eastern Shore states that these facilities are more costly than linear pipeline projects.¹⁰⁸ CH-IV states that the program should be structured in a manner that ensures automatic authorization projects have little impact on ratepayers or interstate pipeline operations and prior notice procedures should be available for projects likely to have significant impacts on ratepayers or interstate pipeline operations.¹⁰⁹

68. As discussed above, we do not propose to include cost limits for LNG blanket activities. However, any section 7 LNG blanket activities would be subject to the same rate treatment applicable under the section 7 pipeline blanket program and our proposed regulations include reference to the relevant portions of the pipeline blanket regulations. Thus, for section 7 LNG activities completed under the automatic authorization category, we propose that the costs be presumptively eligible for rolled-in rate treatment because the eligible activities will be for enhanced reliability and safety.¹¹⁰ As for activities completed under the prior notice category, we note that the Commission is proposing changes to its section 7 pipeline blanket program to allow for incremental rates and any changes made in that proceeding would apply to the section 7 LNG blanket activities.¹¹¹

6. Replacements Under § 2.55 for Section 7 LNG Plants

69. Currently, section 7 LNG certificate holders can replace facilities that “have or will soon become physically deteriorated or obsolete” under § 2.55 of the Commission's regulations.¹¹² Such a replacement must have a substantially equivalent design capacity, be located in the same right-

of-way or on the same site as the facilities being replaced, and be constructed using the temporary work space used to construct the existing facility.¹¹³ Section 2.55 also allows LNG certificate holders to construct auxiliary installations, which includes installations for more efficient or economical operation.¹¹⁴ As the activities that are eligible under § 2.55 would be redundant with the activities under the proposed LNG blanket authorization program, we propose to remove the eligibility for section 7 LNG facilities, including auxiliary systems, under § 2.55 for those entities that choose to apply for and receive a blanket authorization. To ensure that the activities undertaken pursuant to § 2.55 meet the same safety and engineering conditions as those done under the proposed blanket authorization program, we will also require that section 7 LNG plant operators comply with the requirements in § 153.106(c) and § 153.107(a)(3) and (4) for activities undertaken pursuant to § 2.55. Recognizing that LNG certificate holders may have planned projects under § 2.55 and that a sunset period may accordingly be necessary to avoid unwarranted disruption, we propose to include a provision that would make the proposed amendments to § 2.55 effective 2 years after the effective date of the rule. After that time, LNG certificate holders with effective blanket authorizations would have to rely exclusively on the provisions of the LNG blanket program.

C. Blanket Authorization Procedures

1. Obtaining Blanket Authority

70. When instituting the section 7 pipeline blanket certificate program in 1982, the Commission required each existing certificate holder to apply for a blanket certificate¹¹⁵ and delegated authority to staff to act on such applications.¹¹⁶ Applying NGA section 7(e)'s standards, staff issued approximately 65 blanket certificate orders to existing section 7 pipeline companies in the first two years.¹¹⁷

¹¹³ *Id.*

¹¹⁴ *Id.* 2.55(a).

¹¹⁵ Order No. 234, FERC Stats. & Regs. ¶ 30,368 at 30,201; *see also* 18 CFR 157.204 (section 7 pipeline blanket certificate application procedures).

¹¹⁶ 18 CFR 375.308(v)(8).

¹¹⁷ *E.g., E. Tenn. Nat. Gas Co.*, 20 FERC ¶ 62,413 (1982) (finding the “applicant is able and willing properly to do the acts and to [perform] the service proposed and to conform to the provisions of the Natural Gas Act and the requirements, rules, and regulations of the Commission thereunder”) (citing NGA section 7(e), 15 U.S.C. 717f(e)).

¹⁰⁰ *See* 18 CFR 157.202(b)(2)(i).

¹⁰¹ NOI, 193 FERC ¶ 61,141 at P 13, Question B7.

¹⁰² *See supra* P 11 & note 21.

¹⁰³ *See* Cheniere January 26, 2026 Comments at 6; BLUE January 23, 2026 Comments at 3; Woodside January 26, 2026 Energy Comments at 2.

¹⁰⁴ States January 26, 2026 Comments at 8–9.

¹⁰⁵ *See Hackberry LNG Terminal, L.L.C.*, 101 FERC ¶ 61,294, at P 21 (2003) (citing Energy Policy Act of 1992, Pub. L. 102–486, 106 Stat. 2776 (1992)) (noting that the prices, terms, and conditions of service for first sales of natural gas, including sales of imported LNG, have been deregulated by statute and finding there is no regulatory need to require a tariff and rate schedule as a condition of approving an LNG terminal under section 3).

¹⁰⁶ NOI, 193 FERC ¶ 61,141 at P 13, Question B7.

¹⁰⁷ *Id.* at 4.

¹⁰⁸ *Id.*

¹⁰⁹ CH-IV January 16, 2026 Comments at 6.

¹¹⁰ *Certification of New Interstate Nat. Gas Pipeline Facilities*, 88 FERC ¶ 61,227, at 61,746 n.12 (1999).

¹¹¹ *See Revisions to the Blanket Certificate Program*, 91 FR 31371 (May 27, 2026), 195 FERC ¶ 61,128 (2026).

¹¹² 18 CFR 2.55(b).

When a new natural gas company¹¹⁸ requests a certificate to construct and operate interstate transportation facilities, it typically also requests a section 7 pipeline blanket certificate, and the Commission acts on such requests in the certificate proceeding for the project.¹¹⁹

71. The NOI sought comment on whether the Commission should require LNG authorization and certificate holders to apply for a blanket authorization as it does for natural gas pipeline companies.¹²⁰ The NOI also sought comment on whether, and if so how, the Commission should consider an applicant's compliance history when determining whether to grant blanket authorization.

72. Industry commenters generally support the automatic grant of LNG blanket authority to existing authorization and certificate holders and inclusion of a new standard condition in any future section 3 authorization orders.¹²¹ Other commenters request that the Commission require LNG authorization and certificate holders to apply for a blanket authorization.¹²² Earthjustice states that requiring authorization and certificate holders to request a blanket authorization would not be burdensome and would allow the public to comment and provide perspective on whether specific authorization and certificate holders should not be granted a blanket authorization.¹²³

73. Cheniere does not recommend considering prior compliance history.¹²⁴ Similarly, CLNG does not recommend considering prior compliance history unless there is an egregious record or a history of not being forthright in reporting to the Commission.¹²⁵ CLNG notes that the Commission's Office of Enforcement could address any compliance issues.¹²⁶ Other commenters propose that the Commission consider the company's compliance history when acting on a request for a blanket authorization and

retain the ability to revoke such authorization.¹²⁷

74. We propose in § 153.104 to require LNG authorization and certificate holders to apply for blanket authorization before availing themselves of the proposed LNG blanket program.¹²⁸ This appropriately mirrors the approach taken under the section 7 pipeline blanket certificate program. We also propose to establish a delegation for the Director of the Office of Energy Projects (OEP) to act on such requests, to avoid the need for the Commission to address each case.¹²⁹ By requiring LNG authorization and certificate holders to apply for a blanket authorization, Commission staff will ensure that the authorization or certificate holder has requisite plans and procedures in place (such as an Emergency Response Plan as required under NGA section 3A). Finally, we note, consistent with other authorizations, that the Commission retains authority to rescind or decline to grant a blanket authorization for non-compliance.¹³⁰

2. Stakeholder Notification

75. The NOI sought comment on what stakeholder notification the Commission should require for projects constructed pursuant to an LNG blanket program.¹³¹

76. In response to the NOI, CLNG proposes that for projects requiring prior notice, the Commission adopt procedures consistent with § 157.6(d), which requires notification of "all affected landowners and towns, communities, and local, state and Federal governments and agencies involved in the project."¹³² In addition, CLNG proposes that notification also be provided to all customers of the requesting LNG facility.¹³³ Cheniere proposes a more circumscribed approach, stating that notification should be limited to agencies with jurisdictional authority and affected landowners only when activities occur outside the existing, previously-authorized plant boundary; otherwise,

routine in-boundary modifications should not require public notice.¹³⁴

77. We propose to establish landowner notification procedures akin to the Commission's existing regulations for the section 7 pipeline blanket program.¹³⁵ For automatic authorization projects, the notification procedures proposed in § 153.103(d)(1) would require LNG blanket authorization holders to notify affected landowners, as defined by the Commission's regulations,¹³⁶ 45 days prior to commencing construction unless the activity does not involve ground disturbance, changes to operational air and noise emissions, or adverse effects on hazards or safety. In addition to the landowner notification procedures, we propose to add a requirement for automatic authorization activities that each local municipality (*i.e.*, the city, town, or similar local political subdivision) in which the LNG terminal or plant is located be notified, subject to the same exclusion applicable to landowner notification. For prior notice projects, blanket authorization holders would be required, as proposed in § 153.103(d)(2), to notify affected landowners and each local municipality (*i.e.*, the city, town, or similar local political subdivision) in which the LNG terminal or plant is located within at least three business days following the date that a docket number is assigned to the request and at the time the blanket authorization holder initiates easement negotiations. Last, notification to certain Federal, state, and local agencies is required under specified circumstances, as discussed in section III.E.

3. Advance Notice for Automatic Authorization Activities

78. Section 2.55(b) requires notice to the Commission prior to the commencement of construction of certain larger-scale replacement projects because the Commission determined that, consistent with NEPA,¹³⁷ it needed to review replacement activities that could pose serious, adverse environmental impacts before they occur.¹³⁸ The NOI sought comment on whether the Commission should require advance notification to Commission staff of blanket activities prior to

¹¹⁸ Under the NGA a "natural gas company" is defined as a person engaged in the transportation of natural gas in interstate commerce, or the sale in interstate commerce of such gas for resale. 15 U.S.C. 717a(6).

¹¹⁹ *E.g.*, *Double E Pipeline, LLC*, 173 FERC ¶ 61,074, at P 38 (2020); *Adelphia Gateway, LLC*, 169 FERC ¶ 61,220, at P 52 (2019).

¹²⁰ NOI, 193 FERC ¶ 61,141 at P 13, Question A1 (citing 18 CFR 157.204(a)).

¹²¹ Center for LNG January 26, 2026 Comments at 21; Cheniere Energy, Inc. January 26, 2026 Comments at 4.

¹²² *E.g.*, BLUE January 23, 2026 Comments at 3.

¹²³ Earthjustice January 26, 2026 Comments at 7.

¹²⁴ Cheniere January 26, 2026 Comments at 4.

¹²⁵ CLNG January 26, 2026 Comments at 21–22.

¹²⁶ *Id.* at 21–22.

¹²⁷ CH–IV January 16, 2026 Comments at 2; BLUE January 23, 2026 Comments at 3.

¹²⁸ As with the section 7 pipeline blanket certificate program, a new applicant can request a blanket authorization concurrently with its request for authorization under section 3 or section 7.

¹²⁹ See 18 CFR 375.308(v)(8) (delegation to the Director of OEP to approve blanket certificate applications).

¹³⁰ See Order No. 234, FERC Stats. & Regs. ¶ 30,368 at 30,203 (explaining, in the section 7 blanket pipeline certificate proceeding, that the Commission has "the authority to revoke any certificate, including a blanket certificate, under appropriate circumstances").

¹³¹ NOI, 193 FERC ¶ 61,141 at P 13, Question A7.

¹³² CLNG January 26, 2026 Comments at 25.

¹³³ *Id.*

¹³⁴ Cheniere January 26, 2026 Comments at 5.

¹³⁵ 18 CFR 157.203(d). See *infra* section III.C.8.

¹³⁶ *Id.* 157.6(d)(2).

¹³⁷ NEPA requires Federal agencies to analyze the reasonably foreseeable effects of a proposed major Federal action. 42 U.S.C. 4332, *et seq.*

¹³⁸ *Revisions to Regs. Governing NGPA Sec. 311 Constr. & the Replacement of Facilities*, Order No. 544, 57 FR 46487 (Sept. 21, 1992), FERC Stats. & Regs. ¶ 30,951, at 30,686–87 (1992) (cross-referenced at 60 FERC ¶ 61,253).

implementation and, if so, whether 30 days is sufficient.¹³⁹

79. Numerous commenters state that no advance notice should be required for automatic authorization projects.¹⁴⁰ CH-IV recommends a 30-day notice procedure.¹⁴¹

80. We do not propose to require advance notice for the relatively minor activities eligible for automatic authorization, beyond the proposed semi-annual operational reporting discussed below in section III.C.7, and the inspection requirements that are included in each authorization order. The proposed activities that would be eligible for automatic authorization are well-understood and must not result in significant environmental effects. Moreover, the technical reviews, inspections, and semi-annual operational reporting requirements already ensure that staff is aware of any significant modifications.

4. Notice and Protest Procedures for Prior Notice Projects

81. The NOI sought comment on whether the Commission should adopt the same prior notice procedures as in the section 7 pipeline blanket regulations.¹⁴² The NOI also asked which types of protests should be dismissed, if any.¹⁴³

82. Most commenters recommend that the Commission adopt a process similar to the prior notice procedures used in the section 7 pipeline blanket program. Both Cheniere and BLUE recommend that the Commission adopt the same 60-day prior notice timeline.¹⁴⁴ Conversely, and as discussed above, CLNG recommends a two-tiered approach where smaller projects would have a 30-day timeline and larger projects (e.g., new liquefaction trains, tanks, and marine berths) would have a 60-day timeline.¹⁴⁵

83. As for limiting potential range of eligible protestors, CLNG proposes that the Commission limit eligible protestors to customers of the LNG plant and adjacent landowners who can show that they may be affected by the prior notice project in a different manner than by the project approved in the original section 3 authorization. CLNG asserts that these

restricted eligibility criteria would prevent individuals or groups without demonstrated and tangible interests in a project from delaying it.¹⁴⁶ CLNG also proposes that the Director of OEP be authorized to dismiss protests and be required to dismiss any protest that seeks to relitigate the section 3 authorization or other earlier proceedings.¹⁴⁷

84. BLUE proposes that the Director of OEP have 30 days to dismiss a protest if it does not raise a substantive issue, thus providing staff more time to review the filings than under the section 7 pipeline blanket program, under which the Director of OEP has only 10 days to issue such a dismissal.¹⁴⁸

85. Woodside supports the establishment of minimum requirements that a protest must satisfy. Specifically, Woodside states that a protest should be required to: (i) identify with particularity the substantive issue presented by the activity; (ii) set forth in detail the substantive basis for the protest; and (iii) establish with substantial supporting evidence that the protestor or the individuals it represents stand to be materially and substantially affected in an adverse manner by the activity.¹⁴⁹

86. As discussed above, we propose that the regulations establish a tiered approach for the notice and protest procedures for prior notice activities. We propose to establish a 60-day comment period as the foundation for the LNG blanket authorization program and a longer 90-day comment period for a second tier of larger prior notice activities (e.g., liquefaction trains, storage tanks, and marine berths).

87. A shorter time period would be too restrictive to allow interested parties, including state and local agencies who, within 30 days, might furnish an advisory report under NGA section 3A(c),¹⁵⁰ to review the request, and then for Commission staff to perform its review of environmental and safety issues, respond to any issues raised, and protest if necessary.

88. For larger-scale facilities, we propose to establish a 90-day notice period. This longer notice period will provide stakeholders and the Commission sufficient time to evaluate environmental and safety effects

associated with the construction and operation of such facilities while still providing a more streamlined approval process as compared to a full section 3 or 7 application. Based on its decades of experience analyzing such projects, the Commission does not believe a shorter notice period would be appropriate for these larger scale facilities.

89. Regarding eligibility criteria for protestors, we propose to adopt the same approach as our current part 157, subpart F regulations governing protests. Under those regulations, a protest to a prior notice is dismissed if it fails to “raise a substantive issue and fails to provide any specific detailed reason or rationale for the objection.” We note that the Director of the Office of Energy Projects dismisses protests for failure to raise substantive issues pertaining to the project and failure to provide any specific detailed reason or rationale for objecting to the pending proposal, thereby allowing the project to proceed under a blanket authorization.¹⁵¹ However, we seek comment on whether establishing more prescriptive criteria for protestors could focus prior notice proceedings and help promote the intended efficiencies of the blanket program. This could include limiting the persons that may protest a prior notice request to only those with a substantial interest, Commission staff, and affected landowners, so as to preclude protests based solely on generic or irrelevant concerns. We therefore seek comment on the following:

- Whether, and if so how, to establish eligibility criteria so that only persons with a demonstrated substantial interest may protest;
- Other potential defined eligibility criteria for protestor eligibility, including adopting criteria similar to the Commission’s intervention standards¹⁵² and whether the Commission should require membership organizations seeking to protest prior notice requests to provide evidence that they have a member in the relevant geographic area, or are representing a specific member that is or will be directly affected by the proposed project. Any proposals should demonstrate how the criteria do not prevent persons meaningfully impacted by a proposed project from protesting;
- Whether the Commission should establish a designated timeline within

¹³⁹ NOI, 193 FERC ¶ 61,141 at P 13, Question A4.a.

¹⁴⁰ BLUE January 23, 2026 Comments at 4–5; Cheniere January 26, 2026 Comments at 5; CLNG January 26, 2026 Comments at 22.

¹⁴¹ CH-IV January 16, 2026 Comments at 2. See 18 CFR 2.55(b)(2).

¹⁴² NOI, 193 FERC ¶ 61,141 at P 13, Question A6 (citing 18 CFR 157.205).

¹⁴³ *Id.*

¹⁴⁴ Cheniere January 26, 2026 Comments at 4; BLUE January 23, 2026 Comments at 3.

¹⁴⁵ CLNG January 26, 2026 Comments at 17.

¹⁴⁶ *Id.* at 24.

¹⁴⁷ *Id.* at 17.

¹⁴⁸ BLUE January 23, 2026 Comments at 7.

¹⁴⁹ Woodside January 26, 2026 Comments at 1–2.

¹⁵⁰ 15 U.S.C. 717b–1(c). Although section 3A does not apply to section 7 LNG approvals, a 60-day notice period is still appropriate to provide stakeholders time to review a proposal and to provide staff sufficient time to complete any environmental review.

¹⁵¹ *Transwestern Pipeline Co., LLC*, 194 FERC ¶ 62,131 (2026); *S. Star Cent. Pipeline, Inc.*, 194 FERC ¶ 62,097 (2026); *Nw. Pipeline LLC*, 194 FERC ¶ 62,021 (2026).

¹⁵² 18 CFR 385.214(b)(2); *Am. Elec. Power Servs. Corp.*, 120 FERC ¶ 61,052, at P 12 (2007).

which it will seek to issue orders adjudicating prior notice protest proceedings (e.g., 60 days), noting that individual cases present differing issues and information needs, and thus require differing processing times. We also seek comment on whether such procedures would inhibit blanket authorization holders and protestors from negotiating a settlement that would resolve the protest.

5. Notice To Proceed With Construction

90. The NOI sought comment on whether the Commission should require blanket authorization holders to request a notice to proceed from the Director of OEP or the Director's designee prior to the start of construction, introduction of hazardous fluids, or other milestones.¹⁵³

91. CLNG opposes requiring blanket authorization holders to obtain notices to proceed with blanket activities, except for any automatic activities that exceed the footprint of the underlying authorization, for which it recommends requiring a notice to proceed prior to the start of construction.¹⁵⁴ Cheniere opposes requiring notices to proceed for blanket activities altogether, asserting that this requirement poses an unnecessary administrative burden.¹⁵⁵

92. CH-IV and BLUE support requiring notices to proceed. BLUE recommends that the Commission require LNG blanket authorization holders to submit one or multiple implementation plans for site preparation, construction, commissioning, hazardous fluid introduction, and in-service, all of which would require a notice to proceed.¹⁵⁶ CH-IV states that requiring notices to proceed would ensure compliance with safety and environmental measures.¹⁵⁷

93. We do not propose to require notices to proceed for blanket activities under an automatic authorization. These activities are well understood and would not result in changes to hazards and safety, and environmental effects will be analyzed in the programmatic NEPA document that will be prepared for this rulemaking. Further, the LNG blanket authorization holder will need to report automatic authorization activities in its semi-annual report under proposed § 153.106(c)(2).

94. As for prior notice activities, we propose to require: (1) a notice to proceed for the commissioning or introduction of hazardous fluids or to ensure all necessary safety and security systems are installed and functional, and (2) a notice to commence service. Requiring just two notices would reduce the burden on both industry and Commission staff given that a typical case-specific proceeding may involve hundreds of notices to proceed for each new construction activity. The proposed approach also balances safety and security checks done in coordination with other Federal agencies. Although such notices are not required for section 7 pipeline blanket activities, the proposed regulations would require blanket authorization holders to request notices to proceed for section 7 LNG prior notice activities due to the Commission's role in maintaining safety and security oversight in coordination with other Federal agencies throughout the life of an LNG plant.

6. In-Service Deadline

95. The NOI sought comment on whether the Commission should require completion of construction and in-service of blanket projects within a specified timeframe and, if so, what timeframe.¹⁵⁸

96. CLNG and BLUE do not recommend that the Commission include any in-service timeline as part of an LNG blanket program.¹⁵⁹ Cheniere comments that blanket activities should be completed "within normal operational schedules."¹⁶⁰

97. We propose to require section 3 LNG activities under a blanket authorization to be constructed and made available for service within five years of the date on which the activity is deemed authorized. This is the standard deadline included in orders amending authorizations under section 3 and therefore should allow sufficient time to complete proposed blanket activities.¹⁶¹ We propose to adopt the same five-year time limit for section 7 LNG facilities constructed pursuant to a blanket authorization.

7. Reporting Requirements

98. Semi-annual operational reports are required by authorization orders and must "identify changes in facility design and operating conditions" and "plant

modifications, including future plans and progress thereof," and include a section entitled "Significant Plant Modifications Proposed for the Next 12 Months."¹⁶²

99. The NOI sought comment on whether the Commission should require blanket authorization holders to document automatic authorization activities undertaken during the previous calendar year in semi-annual operational reports and, if so, what information should be required to be included.¹⁶³

100. CLNG, the Center for Regulatory Freedom, and Cheniere support using the semi-annual operational reports to report any activities undertaken automatically pursuant to a blanket authorization program.¹⁶⁴ CLNG proposes that each semi-annual operational report include a list of projects undertaken under blanket authorization, along with descriptions and completion dates for each project.¹⁶⁵ CLNG also proposes that blanket authorization holders would demonstrate PHMSA compliance, if required, in the operational reports.¹⁶⁶ CLNG proposes that if a blanket authorization holder files the details of a blanket project as privileged, the blanket authorization holder would provide a public version that identifies the type of project and its general title.¹⁶⁷ BLUE comments that semi-annual operational reports should include a description, any applicable environmental permits and certifying statements that applicable state and Federal permits were obtained, a management of change process, updated design details, and, if needed, demonstration of PHMSA compliance.¹⁶⁸

101. States express concern with the lack of publicly available information regarding activities at LNG plants.¹⁶⁹ States and Earthjustice express the general concern that activities approved subject to an automatic authorization might not be disclosed to the public until blanket authorization holders' semi-annual operational reports that

¹⁶² See, e.g., *Corpus Christi Liquefaction, LLC*, 190 FERC ¶ 61,149 at app. A, env't condition 100.

¹⁶³ NOI, 193 FERC ¶ 61,141 at P 13, Question A4(b).

¹⁶⁴ CLNG January 26, 2026 Comments at 14; Center for Regulatory Freedom January 26, 2026 Comments at 11; Cheniere January 26, 2026 Comments at 5.

¹⁶⁵ CLNG January 26, 2026 Comments at 14.

¹⁶⁶ See *id.* at 35.

¹⁶⁷ *Id.* at 14–15.

¹⁶⁸ BLUE January 23, 2026 Comments at 5.

¹⁶⁹ States January 26, 2026 Comments at 16–17.

¹⁵³ NOI, 193 FERC ¶ 61,141 at P 13, Question D4.

¹⁵⁴ CLNG January 26, 2026 Comments at 48.

¹⁵⁵ Cheniere January 26, 2026 Comments at 7.

¹⁵⁶ BLUE January 23, 2026 Comments at 7. BLUE specifies in its response to NOI Question C1 that implementation plans would be needed for authorized prior notice activities. *Id.*

¹⁵⁷ CH-IV January 16, 2026 Comments at 9.

¹⁵⁸ NOI, 193 FERC ¶ 61,141 at P 13, Question A8.

¹⁵⁹ CLNG January 26, 2026 Comments at 25; BLUE January 23, 2026 Comments at 4.

¹⁶⁰ Cheniere January 26, 2026 Comments at 5.

¹⁶¹ See, e.g., *Corpus Christi Liquefaction, LLC*, 190 FERC ¶ 61,149 at ordering para. (B); *Elba Liquefaction Co., L.L.C.*, 189 FERC ¶ 61,133, at ordering para. (E) (2024).

would be filed after the activities were completed.¹⁷⁰

102. We propose that blanket authorization holders be required to report automatic authorization activities completed under the blanket authorization program using the existing semi-annual operational reports. As explained above, activities eligible for automatic authorization are so well understood as an established industry practice that little scrutiny is required to determine that they are, for section 3 terminals, not inconsistent with the public interest or, for section 7 plants, in the public convenience and necessity.¹⁷¹ Although automatic authorization activities might not be disclosed to the public until after their completion, requiring their inclusion in semi-annual operational reports will provide the public information on a more expedited basis than pursuant to our annual reporting requirement for automatic activities undertaken under the section 7 pipeline blanket program, with respect to which we have not encountered timeliness concerns.¹⁷² In our proposed regulations, at §§ 153.106(c)(2) and 153.107(a), we require blanket authorization holders to report a description of the facilities installed; the specific purpose, location, and beginning and completion date of construction of the facilities installed, the date service commenced, and, if applicable, a statement indicating the extent to which the facilities were jointly constructed; a description of the contacts made, reports produced, and results of consultations which took place to ensure compliance with the NHPA, Coastal Zone Management Act (CZMA), ESA, and NGA; documentation, including images, showing that restoration of work areas is progressing appropriately; and a discussion of problems or unusual construction issues, including those identified by affected landowners, and corrective actions taken or planned. We remind blanket authorization holders that the semi-annual report must conform with the Commission's regulations regarding filings and privileged or critical energy infrastructure information (CEII), including the requirement that anything filed under these regulations must include a public version and a justification for the privileged or CEII treatment.¹⁷³ Generally, information pertaining to items such as offsite

emergency response procedures for public notification and evacuation, and construction and operating reporting requirements is subject to public disclosure. In addition to complying with our regulations regarding non-public information, we propose in § 153.107(c) to require that if any of the information provided in paragraphs §§ 153.107(a)(1) or (a)(5) through (13) is filed as non-public, the blanket authorization holder shall file a public summary of all changes undertaken pursuant to blanket authorization.

103. As for reporting costs, for NGA section 3 blanket activities, we do not propose to require any specific reporting because the Commission does not regulate the rates for section 3 LNG terminals.¹⁷⁴ For NGA section 7 activities, we propose, as discussed above in section III.B.5, that blanket authorization holders be required to include the costs associated with LNG facilities or auxiliary systems constructed under an LNG blanket authorization.

8. Delegations to the Director of the Office of Energy Projects

104. We propose to update the delegations to the Director of the Office of Energy Projects in our regulations to conform with the addition of the LNG blanket program. These delegations are proposed at: 18 CFR 375.308(v)(6), to dismiss a protest to a prior notice project that does not raise a substantive issue and fails to provide a specific detailed reason or rationale; 18 CFR 375.308(v)(8), for approving applications for an initial blanket certificate or blanket authorization; 18 CFR 375.308(w)(5), for approving requests for waiver of landowner notification or local municipality notification requirements consistent with the proposed regulations; and 18 CFR 375.308(x)(5), for rejecting requests under the blanket programs that patently fail to comply with the proposed regulations.

D. Environmental and Engineering Conditions

1. Statutory and Regulatory Compliance

105. The NOI sought comment on how blanket activities would comply with enumerated Federal statutes.¹⁷⁵

¹⁷⁴ See *supra* note 105.

¹⁷⁵ NOI, 193 FERC ¶ 61,141 at P 13, Question D2. The NOI listed the following statutes: Rivers and Harbors Act; CWA; Migratory Bird Treaty Act; Fish and Wildlife Coordination Act; Bald and Golden Eagle Protection Act; Marine Protection, Research, and Sanctuaries Act; Marine Mammal Protection Act; ESA; Magnuson-Stevens Fishery Conservation and Management Act; NHPA; Farmland Protection Policy Act; CZMA; Clean Air Act; Pipeline Safety

CLNG comments that compliance with applicable Federal laws, regulations, and permits can be assured by the conditions in the underlying authorization and recommends that the blanket authorization framework require as a condition compliance with Federal permits, including any new permit requirements updated or revised since issuance of the blanket authorization.¹⁷⁶ Cheniere comments that the Commission can rely on established frameworks to ensure compliance with applicable laws.¹⁷⁷

106. Similar to the pipeline blanket program,¹⁷⁸ we propose in § 153.106(b)(2) that LNG blanket activities that involve ground disturbance or increases in operational air emissions, operational noise emissions, or public safety risks must be consistent with all applicable law including: (1) the CWA and the National Pollution Discharge Elimination System Program; (2) the Clean Air Act and air quality regulations and state implementation plans; (3) NHPA; (4) the Archeological and Historic Preservation Act; (5) CZMA; (6) ESA; (7) E.O. 11988 (requiring Federal agencies to evaluate the potential effects of any actions they may take on a floodplain); (8) E.O. 11990 (requiring an evaluation of the potential effects of construction on wetlands); (9) the Wild and Scenic Rivers Act; (10) the National Wilderness Act; (11) the National Parks and Recreation Act; (12) the Magnuson-Stevens Fishery Conservation and Management Act; (13) the Rivers and Harbors Act; (14) the Migratory Bird Treaty Act; (15) the Fish and Wildlife Coordination Act; (16) the Bald and Golden Eagle Protection Act; (17) the Marine Protection, Research, and Sanctuaries Act; (18) the Marine Mammal Protection Act; (19) the Farmland Protection Policy Act; (20) the

Act; Ports and Waterways Safety Act; and Marine Transportation Security Act.

¹⁷⁶ CLNG January 26, 2026 Comments at 35, 44.

¹⁷⁷ Cheniere January 26, 2026 Comments at 6–7.

¹⁷⁸ See 18 CFR 157.206(b)(2) (requiring activities that involve ground disturbance or changes to operational air and noise emissions to be consistent with all applicable law including: (1) the CWA and the National Pollution Discharge Elimination System Program; (2) the Clean Air Act and air quality regulations and state implementation plans; (3) NHPA; (4) the Archeological and Historic Preservation Act; (5) CZMA; (6) ESA; (7) Executive Order (E.O.) 11988 (requiring Federal agencies to evaluate the potential effects of any actions they may take on a floodplain); (8) E.O. 11990 (requiring an evaluation of the potential effects of construction on wetland); (9) the Wild and Scenic Rivers Act; (10) the National Wilderness Act; (11) the National Parks and Recreation Act; and (12) the Magnuson-Stevens Fishery Conservation and Management Act).

¹⁷⁰ *Id.* at 20; Earthjustice January 26, 2026 Comments at 7.

¹⁷¹ See *supra* note 41.

¹⁷² See 18 CFR 157.207.

¹⁷³ See *id.* 388.112(b)(1).

Pipeline Safety Act;¹⁷⁹ (21) the Ports and Waterways Safety Act; (22) the Marine Transportation Security Act and (23) Coast Guard Authorization Act of 2010.¹⁸⁰

107. We also propose in § 153.106(b)(3)(iv) to adopt the requirement of the pipeline blanket program that to be deemed in compliance with the CWA and E.O. 11988, blanket authorization holders must adhere to the FERC Plan and Procedures¹⁸¹ or obtain written approval from staff or the appropriate Federal or state agency for the use of project-specific alternatives.¹⁸²

108. Additionally, we propose adopting the requirements of the pipeline blanket program for compliance with the NHPA, ESA, as proposed to be amended, and CZMA. For NHPA compliance,¹⁸³ we propose in § 153.106(b)(3)(i) that the State or Tribal Historic Preservation Officer, as appropriate, must find that the project would have no effect on historic properties, consistent with the pipeline blanket program.¹⁸⁴ For compliance with the ESA,¹⁸⁵ we propose in § 153.106(b)(3)(ii) that blanket authorization holders must conduct informal consultation and receive a determination from the appropriate

Federal agency that the activity is not likely to adversely affect a listed species or critical habitat or that no further consultation is necessary prior to proceeding under a blanket authorization, consistent with the pipeline blanket program.¹⁸⁶ The Commission, in its May 21, 2026 notice of proposed rulemaking, proposed to revise the pipeline blanket regulations to clarify that for activities for which the certificate holder finds, using appropriate Federal databases such as the FWS's Information for Planning and Consultation website, that an activity has no effect to listed species or critical habitat, the certificate holder need only provide documentation of that finding.¹⁸⁷ We propose to adopt this clarification for the LNG blanket program.

109. For compliance with the CZMA,¹⁸⁸ we propose in § 153.106(b)(3)(iii) that, prior to construction for automatic authorization projects and prior to filing a request for prior notice projects, blanket authorization holders must obtain from the appropriate state agency a determination that the new automatic or prior notice project complies with the state's coastal zone management plan or waive its right of review, consistent with the pipeline blanket program.¹⁸⁹ Coastal States Organization (CSO)¹⁹⁰ comments that “[c]hanges to the footprint of a project, new facilities or operations outside of an existing project, and modifications to operations within a project can create reasonably foreseeable impacts on coastal uses and resources subject to CZMA Federal consistency review.”¹⁹¹ It calls on the Commission to complete a national Federal consistency review and to require that blanket authorization holders secure state review of consistency with the CZMA prior to approving any blanket activities with

reasonably foreseeable coastal effects not covered by a national analysis.¹⁹² Although we do not propose to complete a national Federal consistency review, our proposal to adopt the requirements of the pipeline blanket program for compliance with the CZMA would provide for activity-specific review, as CSO requests.

110. CSO also asserts that any stakeholder notification, public comment, or protest procedures are not on their own adequate to satisfy the CZMA and recommends requiring all data necessary for, and aligning the review timeline with, a Federal or state CZMA consistency review, which CSO states is typically six months.¹⁹³ Instead, we propose that blanket authorization holders independently complete CZMA review prior to constructing automatic authorization projects or prior to filing prior notice requests, such that aligning filing requirements and review timelines is not necessary.

111. Finally, CSO recommends that the Commission restrict any LNG blanket program “to locales where existing LNG facilities and associated data, analyses, and expertise are concentrated.”¹⁹⁴ LNG blanket authorizations would be limited to operators of existing facilities or those which will receive a case-specific authorization or certificate, consistent with CSO's recommendation.

112. The NOI also sought comment on how blanket authorization holders should demonstrate compliance with applicable Federal permitting requirements.¹⁹⁵ CLNG proposes that blanket authorization holders document all consultations and authorizations either in semi-annual operational reports for automatic activities or in prior notice filings.¹⁹⁶ Cheniere recommends that blanket authorization holders certify their adherence to Federal statutes and regulations, including the Clean Air Act (Title V and New Source Review).¹⁹⁷ CH-IV suggests that blanket authorization holders document consultations and authorizations in requests for notice to proceed prior to the start of

¹⁷⁹ The Pipeline Safety Act is the entire collection of laws amending and consolidating the Natural Gas Pipeline Safety Act of 1968 and the Hazardous Liquid Pipeline Safety Act of 1979.

¹⁸⁰ We note that the list of statutes is more comprehensive than that listed in the section 7 blanket certificate program. However, regardless of the statutes listed, blanket certificate and authorization holders must comply with “all applicable laws.”

¹⁸¹ The FERC Plan and Procedures area a set of baseline construction and mitigation measures developed to minimize the potential environmental effects of construction on upland areas, wetlands, and waterbodies. They can be viewed on the Commission's website at: <http://www.ferc.gov/industries/gas/enviro/plan.pdf> and <https://www.ferc.gov/sites/default/files/2020-04/wetland-waterbody-construction-mitigation-procedures.pdf>.

¹⁸² See 18 CFR 157.206(b)(3)(iv).

¹⁸³ The NHPA requires Federal agencies to take into account the effect of any proposed undertaking on properties listed or eligible for listing in the National Register of Historic Places (defined as historic properties) and afford the Advisory Council on Historic Preservation a reasonable opportunity to comment on the undertaking by consulting with the State or Tribal Historic Preservation Officer to determine whether and how a proposed action may affect historic properties and to seek ways to avoid any adverse effects. 54 U.S.C. 306108.

¹⁸⁴ See 18 CFR 157.206(b)(3)(ii); *id.* part 157, subpart F, app. II.

¹⁸⁵ The ESA requires Federal agencies to ensure that their actions are not likely to jeopardize the continued existence of Federally listed threatened or endangered species or result in the destruction or adverse modification of the critical habitat of such species by consulting with the U.S. Fish and Wildlife Service (FWS) or National Marine Fisheries Service if a proposed action may affect a listed species or critical habitat. 16 U.S.C. 1536(a).

¹⁸⁶ See 18 CFR 157.206(b)(3)(i); *id.* part 157, subpart F, app. I.

¹⁸⁷ *Revisions to the Blanket Certificate Program*, 195 FERC ¶ 61,128 at P 89.

¹⁸⁸ The CZMA provides that “[n]o license or permit shall be granted by [a] Federal agency until the state or its designated agency has concurred with the applicant's certification” that “the proposed activity complies with the enforceable policies of the state's approved [coastal management] program and that such activity will be conducted in a manner consistent with the program.” 16 U.S.C. 1456(c)(3)(A). The state's concurrence is conclusively presumed by its failure to act within 6 months of its receipt of the applicant's certification. *Id.*

¹⁸⁹ See 18 CFR 157.206(b)(3)(iii).

¹⁹⁰ CSO represents the nation's coastal states, commonwealths, and territories on policy issues relating to coastal, Great Lakes, and ocean management.

¹⁹¹ CSO January 27, 2026 Comments at 2.

¹⁹² *Id.* at 1–2. The National Oceanic and Atmospheric Administration's regulations allow Federal agencies to provide states with consistency determinations for Federal agency activities that are national or regional in scope and that affect any coastal use or resource of more than one state. 15 CFR 930.36(e)(1).

¹⁹³ *Id.* at 2–3.

¹⁹⁴ *Id.* at 3.

¹⁹⁵ NOI, 193 FERC ¶ 61,141 at P 13, Question C1(1).

¹⁹⁶ See CLNG January 26, 2026 Comments at 21–22.

¹⁹⁷ Cheniere January 26, 2026 Comments at 6–7.

construction, introduction of hazardous fluids, or other milestones.¹⁹⁸ BLUE recommends requiring implementation plans for authorized prior notice activities to document, among other things, consultations and authorizations.¹⁹⁹

113. For automatic authorization activities, we propose in § 153.107(a)(6) that blanket authorization holders document their compliance with the ESA, NHPA, and CZMA, as proposed above, in semi-annual operational reports and in §§ 153.107(a)(7)–(9) that blanket authorization holders provide a list of other federal permits required for the project. For prior notice filings, consistent with the pipeline blanket program, we propose in § 153.108(e)(4) that the request include documentation of compliance with the ESA, NHPA, and CZMA, as proposed above and in §§ 153.108(e)(7)–(9) that the request provide a list of other federal permits that will be required for the proposed project. Staff will reject prior notice requests that do not meet these criteria or consultation requirements.

2. NEPA Compliance and Categorical Exclusions

114. NEPA requires preparation of an Environmental Impact Statement (EIS) for a proposed major Federal action with a reasonably foreseeable significant effect on the quality of the human environment.²⁰⁰ For a proposed action that does not have a reasonably foreseeable significant effect on the quality of the human environment or if the significance of such effect is unknown, the agency shall prepare a more concise Environmental Assessment (EA) unless it finds that the proposed action is covered by a categorical exclusion or is exempt from NEPA review under another law.²⁰¹ A categorical exclusion describes a category of actions that an agency has determined normally do not result in a significant effect on the human environment and for which, therefore, the preparation of an EIS or EA is not normally required.²⁰²

115. To comply with NEPA for the creation of the LNG blanket program, we direct Commission staff to prepare a NEPA document to assess the environmental effects of projects that may be constructed pursuant to the

automatic authorization as well as the impacts of this rulemaking proceeding.²⁰³ We propose that activities conducted pursuant to prior notice procedures will undergo project-specific NEPA analyses in the form of either (1) a determination that a categorical exclusion is applicable or (2) an EA, as occurs under the pipeline blanket program.

116. The NOI sought comment on whether the Commission should establish new categorical exclusions for LNG blanket activities or adopt existing categorical exclusions from other Federal agencies.²⁰⁴ CLNG, CH–IV, and Cheniere support creating new categorical exclusions for actions taken under a blanket authorization program.²⁰⁵ Cheniere supports a categorical exclusion for in-footprint modifications, similar to PHMSA and DOE regulations.²⁰⁶ States oppose the creation of new categorical exclusions for LNG blanket activities.²⁰⁷ They state that unlike the categorical exclusion for pipeline blanket activities determined by the Commission to normally have no significant effect on the human environment, the Commission has not similarly evaluated any category of LNG activities.²⁰⁸ According to States, activities outside of an LNG plant's footprint would likely involve significant impacts not analyzed in the underlying authorization that would require preparation of an EIS or EA and may not be categorically excluded.²⁰⁹ The Delaware Riverkeeper Network²¹⁰ also opposes any expansion of categorical exclusions for LNG facilities, stating that “[c]limate impacts are cumulative by nature and cannot be meaningfully addressed through generic assumptions or categorical exclusions.”²¹¹

117. We do not propose to establish any categorical exclusions in this rulemaking. Should the Commission determine that certain activities normally do not result in a significant effect on the human environment and

for which, therefore, the preparation of a NEPA document is not required, we will initiate a new proceeding to establish categorical exclusions.

3. Standard Conditions

118. The NOI sought comment on what Federal requirements could be relied upon, and what conditions the Commission should adopt, to minimize the impacts of LNG blanket projects.²¹² Commenters cite various Federal laws (e.g., the Clean Air Act, CWA, Rivers and Harbors Act, and ESA) as well as PHMSA, USCG, and other Federal regulations and the conditions of the underlying authorization order, which could be relied upon to ensure that a blanket authorization project would not have significant impacts.²¹³ Due to the individualized and tailored nature of the conditions included in NGA section 3 authorizations, CLNG recommends that the Commission require LNG blanket authorization holders to abide by the terms and conditions of underlying authorizations.²¹⁴ It also asserts that the Commission's existing inspection process provides the necessary oversight to ensure that blanket authorizations do not compromise safety or environmental protection.²¹⁵ BLUE supports the Commission requiring compliance with certain standard conditions as part of the LNG blanket program and specifically identifies various conditions regarding design details, delegated authority to the Director of OEP, and compliance with the conditions of the underlying authorization.²¹⁶ Woodside indicates that the US Army Corps of Engineers' Nationwide Permitting system could serve as a model, favorably citing its tiered approach and interagency collaboration.²¹⁷

119. Similar to the pipeline blanket program,²¹⁸ we propose in § 153.106(b) to adopt a standard set of conditions with which blanket authorization holders would be required to comply when carrying out both automatic and prior notice activities as part of the LNG blanket program. This will provide for regulatory certainty and ease of implementation. The conditions are based on the Commission's extensive experience with the types of activities

¹⁹⁸ CH–IV January 16, 2026 Comments at 7.

¹⁹⁹ BLUE January 23, 2026 Comments at 7.

²⁰⁰ 42 U.S.C. 4336(b)(1).

²⁰¹ *Id.* 4336(a)(2), (b)(2).

²⁰² *Id.* 4336e(1) (defining “categorical exclusion”); *id.* 4336(a)(2), (b)(2) (explaining that an agency is not required to prepare an environmental document for proposed agency actions that are excluded pursuant to a categorical exclusion).

²⁰³ See *infra* section V.B.

²⁰⁴ NOI, 193 FERC ¶ 61,141 at P 13, Question C3.

²⁰⁵ CLNG January 26, 2026 Comments at 43; CH–IV January 16, 2026 Comments at 8; Cheniere January 26, 2026 Comments at 7.

²⁰⁶ Cheniere January 26, 2026 Comments at 7.

²⁰⁷ States January 26, 2026 Comments at 15.

²⁰⁸ *Id.*

²⁰⁹ *Id.* at 16 & n.56.

²¹⁰ The Delaware Riverkeeper Network is a nonprofit 501(c)(3) membership organization that works throughout the entire Delaware River Watershed on the issues, actions, regulations, legislation, policies, programs and decisions that impact the health of the Delaware River Watershed waterways.

²¹¹ Delaware Riverkeeper Network January 26, 2026 Comments at 1, 3 (citing *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 97 (1983)).

²¹² NOI, 193 FERC ¶ 61,141 at P 13, Questions D1, D3.

²¹³ CLNG January 26, 2026 Comments at 44;

Cheniere January 26, 2026 Comments at 6.

²¹⁴ CLNG January 26, 2026 Comments at 47.

²¹⁵ *Id.* at 44.

²¹⁶ BLUE January 23, 2026 Comments at 8.

²¹⁷ Woodside Energy January 26, 2026 Comments at 3.

²¹⁸ See 18 CFR 157.206.

that we propose to be eligible for blanket authorization. The proposed standard environmental conditions require, among other things: (1) compliance with all applicable laws, including enumerated Federal environmental statutes;²¹⁹ (2) that blanket activities not have a significant adverse effect on a sensitive environmental area, as defined at § 157.202(b)(11) of the pipeline blanket regulations; and (3) that blanket activities comply with certain noise criteria. The conditions also subject LNG blanket activities to: (1) standard engineering requirements as well as regular technical reviews and site inspections by Commission staff; (2) semi-annual reporting; and (3) reporting of significant non-scheduled events.

120. Regarding engineering design conditions, we propose in § 153.106(c) to require blanket authorization holders to provide standard engineering information. For prior notice projects, this engineering information would be filed prior to construction of final design and require that, prior to introduction of hazardous fluids or implementation of an uprate, the company shall have all safety and security systems installed and functional, and request and receive written approval from the Director of OEP, or the Director's designee. This would allow staff to further ensure that facilities are safe and secure prior to activities that may result in safety impacts.

E. Statutory and Regulatory Compliance Conditions

1. Pre-Filing Waiver

121. In NGA section 3A(a), Congress directed the Commission to promulgate regulations requiring a pre-filing process of at least six months prior to the filing of an application for authorization to construct an NGA section 3 LNG terminal and encouraging applicants to cooperate with state and local officials.²²⁰ Although the statute requires a mandatory pre-filing process only for prospective applicants for new LNG terminals, the Commission's pre-filing procedures at § 157.21(a) of our regulations also require operators to use the pre-filing process for modifications to existing NGA section 3 LNG facilities and related jurisdictional natural gas facilities that involve unaddressed significant state and local safety considerations.²²¹ However, pre-filing is

not required where the Director of OEP determines that prospective modifications do not involve significant state and local safety considerations that have not been previously addressed.²²²

122. The NOI sought comment on whether the Commission should waive its pre-filing regulations for blanket activities.²²³ CLNG and Cheniere support waiving the pre-filing requirements.²²⁴ CLNG proposes addressing any state and local safety considerations through updates to the Emergency Response Plans or in prior notice filings but does not specify how.²²⁵ BLUE supports waiving pre-filing if there are no significant safety considerations, including activities with identical configurations to equipment previously evaluated within the existing facility footprint.²²⁶ Stellar Energy²²⁷ suggests that the Commission modify its regulations to require pre-filing only for new LNG terminals or liquefaction trains and not for projects that enhance the efficiency of an existing LNG terminal.²²⁸ CH-IV states that the Commission should consider modifying when or how it waives its pre-filing requirements but does not elaborate.²²⁹

123. States oppose waiving pre-filing procedures for LNG blanket activities, stating that these procedures preserve important statutory consultation and notice rights for impacted state and local agencies regarding LNG activities that implicate significant public safety interests.²³⁰ They further argue that state and local officials are best positioned to determine when a proposed activity involves any significant state or local safety consideration not previously addressed.²³¹

124. Consistent with our aim of providing a streamlined review process for well-understood activities, we propose to waive our pre-filing regulations for LNG blanket activities. This is appropriate not only in light of the blanket program's purposes, but also because the scope of activities that we

throughput requiring additional tanker arrivals or the use of larger vessels; or changing the purpose of the facility from peaking to base load."').

²²² See *id.*

²²³ NOI, 193 FERC ¶ 61,141 at P 13, Question C2.
²²⁴ CLNG January 26, 2026 Comments at 42; Cheniere January 26, 2026 Comments at 7.

²²⁵ CLNG January 26, 2026 Comments at 42.

²²⁶ BLUE January 23, 2026 Comments at 6.

²²⁷ Stellar Energy installs technology to enhance and improve the performance of its customers' turbines, in particular Turbine Inlet Air Chilling systems.

²²⁸ Stellar Energy January 23, 2026 Comments at 4.

²²⁹ CH-IV January 16, 2026 Comments at 7.

²³⁰ States January 26, 2026 Comments at 5.

²³¹ *Id.* at 19.

propose to be eligible for blanket authorization would not involve significant state and local safety considerations that have not been previously addressed. Therefore, waiving pre-filing requirements is consistent with our current regulatory approach. Regarding States' consultation-related concerns, we discuss opportunities for state agency input in greater detail below.²³²

2. PHMSA Letter of Determination

125. PHMSA has exclusive authority under the Pipeline Safety Act to prescribe and enforce minimum safety standards governing the location, design, construction, operation, and maintenance of LNG facilities subject to the jurisdiction of the Commission under the NGA.²³³ PHMSA requires that new, replaced, relocated, or significantly altered LNG facilities comply with its siting regulations at 49 CFR part 193, subpart B. In accordance with an MOU with the Commission, PHMSA examines whether a proposed LNG facility complies with its safety standards and issues a Letter of Determination (LOD) memorializing its review.²³⁴ The issuance of an LOD does not abrogate PHMSA's continuing authority and responsibility over the applicant's compliance with its safety standards during construction and future operation of the facility.

126. The NOI sought comment on how LNG blanket activities would comply with PHMSA regulations.²³⁵ CLNG contends that the PHMSA regulations, inspections, procedures, and structural standards provide adequate regulatory oversight.²³⁶ It specifically points to regulations that require Emergency Response Plans and 60-day notification to PHMSA of rehabilitations, modifications, uprates, replacements, or upgrades of facilities.²³⁷

127. Given the scope of activities that we propose to be eligible for automatic authorization, an LOD would not be required for automatic authorization activities.²³⁸ For prior notice activities,

²³² See *infra* section III.E.5.

²³³ 49 U.S.C. 60101, *et seq.*

²³⁴ Memorandum of Understanding Between the Department of Transportation and the Federal Energy Regulatory Commission Regarding Liquefied Natural Gas Transportation Facilities (Aug. 31, 2018), <https://cms.ferc.gov/media/mou-phmsa-regarding-lng-transportation-facilities-0>.

²³⁵ NOI, 193 FERC ¶ 61,141 at P 13, Question C1(2).

²³⁶ CLNG January 26, 2026 Comments at 36.

²³⁷ *Id.* at 36–37.

²³⁸ Specifically, proposed § 153.108(c)(3)(iii) requires automatic activities not result in significant modification to LNG facilities beyond what was previously evaluated by PHMSA and considered by the Commission.

²¹⁹ See *supra* P 106.

²²⁰ 15 U.S.C. 717b–1(a).

²²¹ 18 CFR 157.21(a) ("Examples of such modifications include, but are not limited to, the addition of LNG storage tanks; increasing

we propose in § 153.108(e)(10) to require that blanket authorization holders obtain from PHMSA and include as part of their request an LOD stating that the blanket activities comply with the federal siting requirements or a letter stating that an LOD is not required. Requests that do not meet these criteria would be rejected by staff.

128. We acknowledge that PHMSA has solicited feedback on potential amendments to the pipeline safety regulations governing LNG plants²³⁹ and we will work with PHMSA to ensure the effectiveness of both of our efforts.

3. USCG Letter of Recommendation

129. Pursuant to the Ports and Waterways Safety Act of 1972 and USCG regulations, operators of NGA section 3 or 7 facilities that receive or send out LNG by waterborne vessel must, prior to construction that would result in an increase in the size or frequency of LNG marine traffic on the associated waterway, submit a Letter of Intent (LOI) to USCG describing, as pertinent, the characteristics of the vessels intended to visit the facility and the frequency of the visits.²⁴⁰ The applicant must also prepare a Waterway Suitability Assessment (WSA)²⁴¹ for review and approval by the USCG. The WSA identifies security threats and safety hazards to LNG marine transportation and identifies appropriate risk management measures.²⁴² The USCG reviews the information provided by the applicant and makes a determination, called a Letter of Recommendation (LOR), on the suitability of the waterway for LNG vessels.²⁴³ Section 813 of the Coast Guard Authorization Act of 2010 also directs USCG to make a recommendation to the Commission as to the suitability of marine traffic associated with a proposed waterside LNG facility,²⁴⁴ and the LOR meets that requirement.

130. The NOI sought comment on how LNG blanket activities would comply with USCG regulations.²⁴⁵ CLNG proposes that blanket authorizations include as a condition a

requirement for an updated LOI or WSA, where required.²⁴⁶ CLNG points to regulations involving one-year notification for increases in the size or frequency of LNG marine traffic, pre-operation annual reviews of WSAs, and the development of emergency manuals as examples of adequate regulatory oversight provided by the USCG.²⁴⁷

131. Given the scope of activities that we propose to be eligible for automatic authorization, a new or updated LOR would not be required for automatic authorization activities.²⁴⁸ Blanket authorization holders would still be required to report modifications to USCG pursuant to applicable laws and regulations.²⁴⁹ For prior notice activities, we propose in § 153.108(e)(11) to require that blanket authorization holders obtain from USCG and include as part of their request a new or updated LOR or a determination that a new or updated LOI, WSA, or LOR is not required. Staff will reject requests that do not meet these criteria.

4. DoW Concurrence

132. NGA section 3(f)(3) directs the Commission to obtain the concurrence of the Secretary of War before authorizing the siting, construction, expansion, or operation of LNG terminals affecting the training or activities of an active military installation.²⁵⁰ This requirement applies only to LNG plants authorized under NGA section 3. As directed by NGA section 3(f)(2), the Commission on November 21, 2007, entered into an MOU with the Secretary of War to ensure coordination and consultation on the siting, construction, expansion, and operation of LNG terminals.²⁵¹

133. The NOI sought comment on how NGA section 3 blanket activities would comply with NGA section 3(f)(3).²⁵² CLNG contends that activities it proposes as eligible for automatic authorization and 30-day prior notice would not rise to the level of requiring

new concurrence from the DoW.²⁵³ It recommends that the Commission consult with DoW to revise their MOU to include “blanket concurrence” for activities undertaken under automatic authorization or prior notice that do rise to the level of requiring a new concurrence.²⁵⁴ CLNG also recommends that the Commission use DoW’s existing informal Clearinghouse process for prior notice activities, assuming concurrence can be received within the 60-day notice period.²⁵⁵ BLUE recommends that prior notice requests document DoW concurrence.²⁵⁶

134. In order to ensure that the blanket authorization program complies with both the letter and the purposes of section 3(f) of the NGA, we propose in §§ 153.107(a)(10) and 153.108(e)(13) to require that blanket authorization holders, for both automatic authorization (prior to construction) and prior notice activities, obtain DoW concurrence using DoW’s informal Clearinghouse process. However, the Commission will continue to explore whether changes to the MOU with DoW could result in certain activities, particularly those subject to automatic authorization, being undertaken without project-specific concurrence. Blanket authorization holders would document their compliance in semi-annual operational reports for automatic authorization activities or in prior notice filings. Prior notice requests that do not meet these criteria would be rejected by staff.

5. State and Local Safety Considerations

135. NGA section 3A(b) requires the Commission to consult with states regarding state and local safety considerations prior to issuing an authorization under NGA section 3.²⁵⁷ Under NGA section 3A(c), states may (but need not) furnish an advisory report on state and local safety considerations no later than 30 days

²⁵³ CLNG January 26, 2026 Comments at 38–39.

²⁵⁴ *Id.* at 39.

²⁵⁵ *Id.* The DoW established the Military Aviation and Installation Assurance Siting Clearinghouse to provide a timely, transparent, and repeatable process to coordinate and oversee the military mission compatibility evaluation process for all energy projects or energy-related projects in the United States. Private parties, state and local officials, and the Commission may request informal reviews to provide preliminary compatibility determinations prior to formal project reviews.

²⁵⁶ BLUE January 23, 2026 Comments at 6–7.

²⁵⁷ 15 U.S.C. 717b–1(b). State and local safety considerations include “(1) the kind and use of the facility; (2) the existing and projected population and demographic characteristics of the location; (3) the existing and proposed land use near the location; (4) the natural and physical aspects of the location; (5) the emergency response capabilities near the facility location; and (6) the need to encourage remote siting.” *Id.*

²³⁹ 90 FR 18949 (May 5, 2025).

²⁴⁰ 33 U.S.C. 1221, *et seq.*; 33 CFR 127.007(a), (c).

²⁴¹ 33 CFR 127.007(e).

²⁴² *Id.* 127.007(f).

²⁴³ 33 CFR 127.009. Factors considered by the USCG under its regulations include: density and characteristics of marine traffic in the waterway; locks, bridges and other man-made obstructions in the waterway; and water depth and tides. *Id.* 127.009(a).

²⁴⁴ Public Law 111–281, 813, 124 Stat. 2905, 2999 (2010).

²⁴⁵ NOI, 193 FERC ¶ 61,141 at P 13, Question C1(3).

²⁴⁶ CLNG January 26, 2026 Comments at 37–38.

²⁴⁷ *Id.* at 37–38 (citing 33 CFR 127.007(a)(1), (e), 127.019, 127.307).

²⁴⁸ Specifically, proposed § 153.108(c)(3)(ii) requires automatic activities not result in an increase in frequency or size of LNG marine vessels at the LNG terminal beyond that previously evaluated in a USCG Letter of Recommendation and considered by the Commission.

²⁴⁹ See 33 CFR pt. 105; 33 CFR pt. 127.

²⁵⁰ 15 U.S.C. 717b(f)(3).

²⁵¹ Memorandum of Understanding Between the Federal Energy Regulatory Commission and the Department of Defense to Ensure Consultation and Coordination on the Effect of Liquefied Natural Gas Terminals on Active Military Installations (Nov. 21, 2007, updated Aug. 29, 2014), <https://www.ferc.gov/media/2007-mou-dod>.

²⁵² NOI, 193 FERC ¶ 61,141 at P 13, Question C1(4).

after an application under section 3 is filed, to which the Commission must specifically respond.²⁵⁸ Additionally, NGA section 3A(d) allows states in which an operational LNG terminal is located to conduct safety inspections and notify the Commission of any alleged safety violations on which the Commission or the appropriate Federal agency shall take appropriate action.²⁵⁹ These requirements apply only to LNG plants authorized under NGA section 3.

136. The NOI sought comment on how NGA section 3 blanket activities would comply with NGA sections 3A(b)–(d).²⁶⁰ CLNG states that existing LNG facility safety standards and air emissions standards under state-administered Clean Air Act programs provide the necessary state oversight to address state and local safety considerations.²⁶¹ CH–IV recommends that blanket authorization holders document that state and local safety considerations have been addressed in requests for notice to proceed prior to the start of construction, introduction of hazardous fluids, or other milestones.²⁶² States raise concerns regarding the compatibility of a blanket authorization program and statutorily required state consultation.²⁶³ They state that the notice and information provided by blanket authorization holders under the current process promote participation by state and local agencies to ensure sufficient conditions are adopted to address the unique safety, security, or environmental impacts associated with the action.²⁶⁴ States assert that a blanket program would undermine public safety and potentially run afoul of consultation requirements, particularly automatic authorization activities, which may not be disclosed to the public until after they are completed.²⁶⁵

137. Given the scope of activities that we propose to be eligible for automatic authorization, we do not think those activities would involve any additional state and local safety considerations not addressed in the underlying authorization. Still, in the proceeding in which the blanket authorization holder receives its blanket authorization, the state designated agency may file comments or an advisory report regarding whether activities eligible for automatic authorization would pose significant safety impacts for that

terminal. The Commission would address the state's concerns in that proceeding.

138. For prior notice activities, we propose in § 153.108(e)(14) to require that blanket authorization holders include as part of their prior notice filing a letter from the state designated agency indicating that the activity does not raise any state or local safety concerns. Alternatively, if such a letter cannot be obtained at the time of filing the prior notice request, the blanket authorization holders shall provide evidence that the state designated agency was notified of the request and that it has 30 days to furnish an advisory report on state and local safety considerations or may protest. The proposed 60- or 90-day notice period would provide states with sufficient time to file an advisory report within the 30-day period specified in NGA section 3A(c). If a state advisory report is filed, staff would protest the prior notice request to allow the Commission sufficient time to specifically respond.

6. Emergency Response Plans

139. NGA section 3A(e) requires that operators develop an Emergency Response Plan, including a cost-sharing plan, in consultation with the USCG and state and local agencies for approval by the Commission prior to construction of an LNG terminal.²⁶⁶ This requirement only applies to LNG plants authorized under NGA section 3.

140. The NOI sought comment on how NGA section 3 blanket activities would comply with NGA section 3A(e).²⁶⁷ CLNG proposes that the Emergency Response Plan submitted with the underlying authorization would suffice for all future actions taken through any blanket authorization.²⁶⁸ BLUE comments that activities undertaken pursuant to a blanket authorization program would require minimal updates to Emergency Response Plans and, for automatic activities, only updates to the drawings typically contained in appendices.²⁶⁹ States comment that blanket activities may require a change in the emergency response and cost-sharing plans.²⁷⁰

141. Given the scope of activities that we propose to be eligible for automatic

authorization, we do not expect those activities would warrant or necessitate any material updates to the emergency response and cost-sharing plans approved in the underlying authorization proceeding. For prior notice activities, we propose in § 153.108(e)(15) that blanket authorization holders obtain from all relevant state and local emergency response organizations and emergency responders, and include as part of their request, letters stating that such activities are consistent with the Emergency Response Plan, including the cost-sharing plan, for the underlying authorization, or that any changes were developed in consultation with them for the proposed activity. Alternatively, if such letters cannot be supplied, blanket authorization holders must supply evidence in their filings that the emergency response organizations and emergency responders have been notified that they may protest the filing.²⁷¹ If the blanket authorization holder believes new or updated plans are needed, the new or updated plans would need to be submitted as part of the prior notice request in order to be approved by the Commission prior to construction.

142. States also raised concerns with the impact of a section 3 blanket authorization program on the availability of data used to inform decisions local and state authorities make in the development of LNG emergency response and cost-sharing plans.²⁷² We reiterate that blanket authorization holders would be required to comply with the Commission's regulations regarding filings and privileged or CEII treatment thereof and that generally, information pertaining to items such as offsite emergency response procedures for public notification and evacuation, and construction and operating reporting requirements, is subject to public disclosure.²⁷³ We also propose to require that if any of the information provided in paragraphs §§ 153.107(a)(1) or (a)(5) through (13) is filed as non-public, the blanket authorization holder

²⁷¹ In the event that the blanket authorization holder is unable to obtain letters because a particular entity does not agree with the conclusion that either no changes to the Emergency Response Plan are needed or that the entity agreed to all changes to the plan, the blanket authorization holder should supply evidence in its filing that the emergency response organizations, emergency responders, and the USCG have been notified that they may protest the filing.

²⁷² States January 26, 2026 Comments at 19.

²⁷³ See *supra* P 102; 18 CFR 388.112(b)(1) (requiring that any document filed under these regulations must include a public version and a justification for privileged or CEII treatment).

²⁵⁸ 15 U.S.C. 717b–1(c).

²⁵⁹ *Id.* 717b–1(d).

²⁶⁰ NOI, 193 FERC ¶ 61,141 at P 13, Question C1(5).

²⁶¹ CLNG January 26, 2026 Comments at 40.

²⁶² CH–IV January 16, 2026 Comments at 7.

²⁶³ States January 26, 2026 Comments at 19–20.

²⁶⁴ *Id.*

²⁶⁵ *Id.* at 20.

²⁶⁶ 15 U.S.C. 717b–1(e).

²⁶⁷ NOI, 193 FERC ¶ 61,141 at P 13, Question C1(6).

²⁶⁸ CLNG January 26, 2026 Comments at 41. CLNG also points to the PHMSA requirement to file and gain approval of an emergency evacuation plan and the USCG requirement to file an emergency manual and receive notice that it has been examined as further emergency preparedness measures. *Id.* at 41–42.

²⁶⁹ BLUE January 23, 2026 Comments at 5.

²⁷⁰ States January 26, 2026 Comments at 19.

shall file a public summary of all changes made under its blanket authorization.

F. Severability

143. We propose to include at § 153.101(d) a proviso that if any provision of the LNG blanket regulations, or the application of any provision thereof to any person or circumstance, is held invalid, the remainder of those regulations and the application thereof to other persons or circumstances shall not be affected thereby. Notably, the regulations proposed herein are not “in any way intertwined” and “operate entirely independently of one another.”²⁷⁴

IV. Request for Comments

144. The Commission requests and encourages public comments on this NOPR. Comments may include any related matters or alternative proposals that commenters may wish to discuss. The Commission will consider comments it receives and provide responses in a final rule, with changes, if warranted.

145. Comments are due December 21, 2026. Comments must refer to Docket No. RM26–2–001 and must include the commenter’s name, the organization they represent, if applicable, and their address in their comments. All comments will be placed in the Commission’s public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

146. The Commission encourages that comments be filed electronically via the eFiling link on the Commission’s website at <http://www.ferc.gov>. The Commission accepts most standard word processing formats. Documents created electronically using word processing software must be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

147. Commenters that are not able to file comments electronically may file an original of their comment by USPS mail or by courier or other delivery services. For submission sent via USPS only, filings should be mailed to: Federal Energy Regulatory Commission, Office

of the Secretary, 888 First Street NE, Washington, DC 20426. Submission of filings other than by USPS should be delivered to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

V. Regulatory Requirements

A. Information Collection Statement

148. The information collection in this proposed rule is being submitted to the Office of Management and Budget (OMB) per its regulations,²⁷⁵ which require that OMB approve certain reporting, record keeping, and public disclosure requirements imposed by an agency.

149. The Commission estimates that the proposed tiered blanket authorization program will enable a subset of projects at LNG facilities to be implemented through either automatic or prior notice authorization while maintaining appropriate oversight and stakeholder engagement. As a result, the proposal would reduce the number of full applications and resultant information collection burden.

150. Natural gas companies and LNG operators file applications with the Commission so it can review the necessary information related to the construction, maintenance, and operation of facilities to provide service or to abandon facilities or service under sections 3 and 7 of the NGA and determine if the requested authorization meets statutory and regulatory requirements and should be granted. This NOPR proposal would provide entities with an opportunity to apply to participate in two new lower-burden filing approaches. To participate in the new approaches, entities must apply for and be granted a blanket authorization:

- *Application for Blanket*

Authorization that includes a brief application, together with evidence that the applicant has the required safety systems, Emergency Response Plans, and appropriate environmental, engineering and operating procedures to support blanket activities.

The proposed lower-burden filing approaches are:

- *Prior Notice Filings* would include a description of the project, purpose, and justification, together with engineering and technical data, and an assessment of any capacity increases or footprint changes and any environmental or safety impacts. The prior notice filings also include evidence of landowner notification, the identification of affected agencies, as

well as any environmental documentation.

- *Automatic Authorizations* that will not require prior filings or applications. These activities must be documented in a semi-annual operational report, which is already required for these projects.

151. These proposed new approaches would be alternatives to the existing full application process, which requires extensive technical, environmental, and economic materials.

The Commission estimates that this proposed rule will affect the following existing information collections:

- *FERC–537: Gas Pipeline Certificate: Construction, Acquisition & Abandonment* (OMB Control No 1902–0060).

- *FERC–539: Gas Pipeline Certificates: Import & Export Related Applications* (OMB Control No 1902–0062).

- *FERC–577: Natural Gas Facilities: Environmental Review and Compliance* (OMB Control No 1902–0128).

152. *Title: FERC–537: Gas Pipeline Certificate: Construction, Acquisition & Abandonment.*

Action: Revision to an existing information collection.

OMB Control No: 1902–0060.

Respondents: Companies proposing natural gas projects under section 7 of the NGA and jurisdictional natural gas companies.

Frequency of Responses: Ongoing. Natural gas companies file the necessary information with the Commission so that it can review the filing of applications for the construction and operation of facilities to provide service or to abandon facilities or service under section 7 of the NGA to determine if the requested authorization should be granted.

Necessity of Information: This information is necessary so that the Commission can fulfill its statutory mandate under the NGA to oversee natural gas infrastructure and facilities.

Proposed Change: The Commission estimates that this NOPR would reduce the number of Interstate Certificate and Abandonment Applications by 1 (from 31 to 30). Note that the Commission published a separate NOPR²⁷⁶ that proposed to reduce the burden associated with these applications by 9 (from 31 to 22). If both of these NOPRs are finalized as proposed, the burden reductions would be added together (e.g., reducing applications by 10 from 31 to 21).

²⁷⁶ *Revisions to the Blanket Certificate Program*, 195 FERC ¶ 61,128.

²⁷⁴ *Davis Cnty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997) (internal quotation marks and citation omitted); *Carlson v. Postal Regul. Comm’n*, 938 F.3d 337, 351 (D.C. Cir. 2019); *Epsilon Elecs., Inc. v. U.S. Dep’t of Treasury*, 857 F.3d 913, 929 (D.C. Cir. 2017); *Tel. & Data Sys., Inc. v. FCC*, 19 F.3d 42, 50 (D.C. Cir. 1994).

²⁷⁵ 5 CFR 1320.11.

Public Reporting Burden: The Commission estimates burden²⁷⁷ and cost as follows:

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ²⁷⁸	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1) ²⁷⁹
18 CFR 157.6 Interstate Certificate and Abandonment Applications ²⁸⁰ .	30	1.39	41.7	500 hrs.; \$51,000	20,850 hrs.; \$2,126,700	\$70,890
Total (impacted collection activities)			41.7		20,850 hrs.; \$2,126,700	

153. *Title:* FERC–539: Gas Pipeline Certificates: Import & Export Related Applications.

Action: Revision to an existing information collection.

OMB Control No: 1902–0062.

Respondents: Companies proposing and reporting natural gas projects under section 3 of the NGA and LNG terminal operators.

Frequency of Responses: Ongoing. Jurisdictional companies file the necessary information with the Commission so that it can review the filing of applications for the construction and operation of facilities to provide service or to abandon facilities or service under section 3 of the NGA to determine if the requested authorization should be granted.

Necessity of Information: This information is necessary so that the

Commission can fulfill its statutory mandate under the NGA to oversee natural gas infrastructure and facilities.

Proposed Change: In order to participate in the blanket authorization program, the Commission proposes that natural gas companies will need to submit an application that is reviewed by the Commission. The Commission anticipates that most or all of the relevant companies will apply to participate in this program over the first three years, after which there would be very few applications, only when a new jurisdictional entity is formed. The Commission estimates that adopting the proposals in this NOPR would reduce the number of applications seeking authorization under Section 3 of the NGA by 2 (from 6 to 4) as a result of companies shifting to using the blanket authorization program. When allowed

by the program rules and regulations, participants could submit prior notice filings instead of full applications. The Commission estimates that there would be 3 Prior Notice Filings each year—2 related to LNG terminals and 1 related to interstate certificate and abandonment.²⁸¹ Program participants would need to include information about any activities completed under the blanket authorization program in their semi-annual operational reports. These reports are already required as a condition of their NGA authorization. The Commission is incorporating this reporting burden into the FERC–539 information collection to reflect that this would be a regulatory requirement.

Public Reporting Burden: The Commission estimates burden and cost as follows:

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response ²⁸²	Total annual burden hours & total annual cost	Cost per respondent (\$)
	(1)	(2)	(1) × (2) = (3)	(4)	(3) × (4) = (5)	(5) ÷ (1) = (6)
18 CFR 153.7 Applications	4	2	8	15 hrs.; \$1,530	120 hrs.; \$12,240	\$3,060
18 CFR 153.104 Blanket Authorization Program—Application ²⁸³ .	25	0.33	8	4 hrs.; \$408	32 hrs.; \$3,264	408
18 CFR 153.103(c) Blanket Authorization Prior Notice Filings.	3	1	3	8 hrs.; \$816	24 hrs.; \$2,448	816
18 CFR 153.106(c) Semi-Annual Operational Reports ²⁸⁴ .	25	2	50	25 hrs.; \$2,550	1,250 hrs.; \$127,500	5,100
Total (impacted collection activities)			69		1,426 hrs.; \$145,452	

154. *Title:* FERC–577: Natural Gas Facilities: Environmental Review and Compliance.

Action: Revision to an existing information collection.

OMB Control No: 1902–0128.

Respondents: Companies seeking authorization to site, design, construct, operate, or modify LNG facilities.

Frequency of Responses: Ongoing. Companies file the necessary information.

Necessity of Information: This information is necessary so that the Commission can fulfill its statutory mandate under the NGA to oversee natural gas infrastructure and facilities.

²⁷⁷ Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

²⁷⁸ Commission staff estimates that the industry's hourly cost for wages plus benefits is similar to the Commission's \$102 FY 2026 average hourly cost for wages and benefits.

²⁷⁹ Each of the figures in this column are rounded to the nearest dollar.

²⁸⁰ This proposed rulemaking would reduce the number of applications. There is no proposed impact on the other parts of this collection.

²⁸¹ Described above in the estimated impacts to the FERC–537 information collection.

²⁸² Commission staff estimates that the industry's hourly cost for wages plus benefits is similar to the Commission's \$102 FY 2026 average hourly cost for wages and benefits.

²⁸³ After the initial applications in the first 3 years, the Commission anticipates that there will only be a new application when a new company enters the market. The Commission estimates this as 1 application every 3 years.

²⁸⁴ These semi-annual operational reports are already required as part of each company's authorization under section 7 or 3 of the NGA. The Commission is incorporating this requirement into the regulations and documenting that shift with this information collection.

Proposed Change: The Commission estimates that this NOPR would reduce the number of companies' environmental review and compliance submissions by 3 (from 107 to 104) as a result of companies shifting to using

the blanket certificate program. This would result in a burden reduction of 9,289 hours and would also significantly decrease the time before a facilities or infrastructure improvement could be implemented enabling the

company to reap the benefits of the improvement more quickly (*e.g.*, additional revenue or decreased costs).

Public Reporting Burden: The Commission estimates burden and cost as follows:

	Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours & average cost per response (\$ (rounded)	Total annual burden hours & total annual cost (\$ (rounded)	Cost per respondent (\$ (rounded)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1) = (6)
Companies' Environmental Review and Compliance ²⁸⁵ (18 CFR Parts 2, 153, 157, and 380).	104	16	1,664	193.52 hours; \$19,932.56 ...	322,017 hours; \$32,845,763	\$318,921
Total (impacted collection activities).			1,664		322,017 hours; \$32,845,763	

The Commission requests comments on:

- the need for this information,
- whether the information will have practical utility,
- the accuracy of the provided burden estimates,
- ways to enhance the quality, utility, and clarity of the information to be collected, and
- any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

155. Send written comments concerning the collection of information(s) and the associated burden estimate(s) to the Commission according to the instructions in this NOPR. You must include the Docket Number and the related OMB Control Number.

B. Environmental Analysis

156. Unless a categorical exclusion or statutory exception applies, the Commission is required to prepare an EA or an EIS for any major Federal action that may have a significant adverse effect on the human environment.²⁸⁶ Accordingly, we direct Commission staff to prepare a NEPA document to assess the environmental impacts of projects that may be constructed pursuant to the automatic authorization. That document will also consider the impact of the action we are taking in this rulemaking proceeding. For prior notice projects, Commission staff will continue to conduct a case-specific analysis, including determining the nature of appropriate environmental

review, *e.g.*, preparation of an environmental document or application of a categorical exclusion.

C. Regulatory Flexibility Act

157. The Regulatory Flexibility Act of 1980 (RFA)²⁸⁷ generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The Commission is not required to make such an analysis if proposed regulations would not have such an effect.

158. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business. LNG facilities are designated under "All Other Support Activities for Transportation" (*i.e.*, NAICS 488999) as small entities if they do not exceed the size standard of \$25 million.²⁸⁸ FERC reviewed the companies operating LNG facilities and is not aware of any with a revenue below \$25 million. Impacts associated with this proposed rule are limited to the avoidance of unintended new obligations that would be imposed on affected small businesses in the absence of a change and therefore are not significant. Accordingly, pursuant to section 605(b) of the RFA, the Commission certifies that the regulations proposed herein should not have a significant economic impact on a substantial number of small entities.

D. Regulatory Planning and Review

159. E.O. 12866 (Regulatory Planning and Review), as amended by E.O. 14215 (Ensuring Accountability for All Agencies) and affirmed by E.O. 13563 (Improving Regulation and Regulatory

Review), directs agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs (OIRA) has determined this regulatory action is a "significant regulatory action," under section 3(f) of E.O. 12866, as amended, though not economically significant under section 3(f)(1). Accordingly, OIRA has reviewed this regulatory action for compliance with the analytical requirements of E.O. 12866.

160. This regulatory action proposes to establish procedures for authorizing activities at LNG plants without a case-specific authorization order from the Commission, which would have the effect of dramatically streamlining the approval of LNG infrastructure projects and would be deregulatory in nature. In particular, the proposed rule would reduce the number of projects subject to the case-specific application process in Part 153 Subpart B by approximately 3 projects per year; this streamlining would result in a burden reduction of 3%. We note that the proposed rule would not change the total number of projects that would be constructed, just the method for obtaining regulatory approval. The proposed rule would result in cost savings to the agency and LNG plant authorization and certificate holders for the projects that would be covered by the proposed rule because it would provide a more streamlined administrative process for project proposals that would otherwise require case-specific review under NGA

²⁸⁵ This is the number of estimated companies anticipated to file environmental related information. This is based on previous years' responses combined with trend information.

²⁸⁶ *Reguls. Implementing the Nat'l Env't Pol'y Act*, Order No. 486, 52 FR 47897 (Dec. 10, 1987), FERC Stats. & Regs. ¶ 30,783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

²⁸⁷ 5 U.S.C. 601–612.

²⁸⁸ 13 CFR 121.101; NAICS Association, 488999—*All Other Support Activities for Transportation*, <https://www.naics.com/naics-code-description/?v=2022&code=221210>.

sections 3 or 7. As reflected in the tables above, we estimate that respondents would save 9,988 hours of effort, which the Commission estimates as a cost savings of \$1,018,776. Moreover, faster approvals would result in additional cost savings and benefits to authorization and certificate holders and their customers. We seek comment on how to quantify those cost savings. Absent this rule, the activities proposed as eligible for an LNG blanket program would be subject to a less streamlined permitting process, resulting in increased administrative costs to the Commission and to authorization and certificate holders. This proposed rule, if finalized as proposed, is expected to be a deregulatory action under E.O. 14192 (Unleashing Prosperity Through Deregulation).

E. Document Availability

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

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

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

164. In accordance with 5 U.S.C. 553(b)(4), a summary of this rule may be found at www.ferc.gov/major-orders-regulations under the NOPR tab.

List of Subjects

18 CFR Part 2

Electric utilities; Natural gas; Pipelines; Reporting and recordkeeping requirements.

18 CFR Part 153

Exports; Imports; Natural gas; Reporting and recordkeeping requirements.

18 CFR Part 375

Authority delegations (Government agencies); Seals and insignia; Sunshine Act.

By direction of the Commission. Commissioner Change is concurring with a separate statement attached. (S E A L)

Issued: October 15, 2026.

Carlos D. Clay,
Deputy Secretary.

In consideration of the foregoing, the Commission proposes to amend parts 2, 153, and 375, title 18, *Code of Federal Regulations*, as follows.

PART 2—GENERAL POLICY AND INTERPRETATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 5 U.S.C. 601; 15 U.S.C. 717–717z, 3301–3432; 16 U.S.C. 792–828c, 2601–2645; 42 U.S.C. 4321–4370h, 7101–7352.

■ 2. Revise § 2.55 to add paragraph (d) and (e):

§ 2.55 Auxiliary system installations and replacement facilities.

* * * * *

(d) *LNG facilities and auxiliary systems at LNG plants.* Beginning [INSERT DATE TWO YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], this section does not authorize a blanket authorization holder, as defined by § 153.102(a)(1) of this chapter, to construct auxiliary installations or replace LNG facilities and auxiliary systems at liquefied natural gas plants.

(e) *Engineering conditions for activities at LNG plants.* Beginning [INSERT DATE TWO YEARS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**], the construction of auxiliary installations at LNG plants and the replacement of facilities at LNG plants are subject to the requirements of § 153.106(c) and § 153.107(a)(3) and (4) of this chapter.

* * * * *

PART 153—APPLICATIONS FOR AUTHORIZATION TO CONSTRUCT, OPERATE, OR MODIFY FACILITIES USED FOR THE EXPORT OR IMPORT OF NATURAL GAS

■ 1. The authority for part 153 is revised to read as follows:

Authority: 15 U.S.C. 717–717z; E.O. 10485, 3 CFR, 1949–1953 Comp., p. 970, as amended by E.O. 12038, 3 CFR, 1978 Comp., p. 136; DOE Delegation Order No. S1–DEL–FERC–2006 (May 16, 2006).

■ 2. Add subpart E to read as follows:

Subpart E—Blanket Authorizations Under Sections 3 and 7 of the Natural Gas Act for LNG Plants

■ 3. Add § 153.101 to read as follows:

§ 153.101 Applicability.

(a) *Scope.* This subpart establishes a procedure whereby a liquefied natural gas (LNG) terminal authorization holder or LNG plant certificate holder may obtain a blanket authorization allowing certain activities under section 3 or 7 of the Natural Gas Act.

(b) *Who may apply.* This procedure is only applicable to LNG terminal authorization holders and LNG plant certificate holders.

(c) *Availability of case-specific authorizations.* Nothing in this subpart shall preclude an LNG terminal authorization holder or LNG plant certificate holder from proceeding under any other provision of the Commission's regulations to obtain Commission authorization under section 3 or 7 of the Natural Gas Act.

(d) *Severability.* If any provision of this subpart, or the application of such provision to any person or circumstance, is held invalid, the remainder of this subpart and the application of such provision to other persons or circumstances shall not be affected thereby.

■ 4. Add § 153.102 to read as follows:

§ 153.102 Definitions.

(a) *Subpart E definitions.* For purposes of this subpart:

(1) *Blanket authorization holder* means any LNG terminal authorization holder or LNG plant certificate holder with an effective blanket authorization issued pursuant to this subpart.

(2) *LNG terminal authorization holder* means a person with an effective authorization issued pursuant to section 3 of the Natural Gas Act to site, construct, or operate an LNG terminal.

(3) *LNG plant certificate holder* means a natural gas company with an effective certificate of public convenience and necessity issued pursuant to section 7 of the Natural Gas Act to construct and operate LNG facilities.

(4) *LNG facilities* means those components of an LNG plant that receive, unload, load, store, transport, gasify, liquefy, or process natural gas. LNG facilities include feed gas facilities; pretreatment facilities; natural gas liquid facilities; heavy hydrocarbon condensate facilities; liquefaction facilities; LNG storage facilities; truck transfer facilities; rail transfer facilities; marine transfer facilities; vaporization or regasification facilities; sendout gas conditioning facilities; and sendout facilities.

(5) *Auxiliary system* means those components of an LNG plant that are not LNG facilities but are necessary to support safe and reliable operation of the plant. Auxiliary systems include vapor handling systems; nitrogen and inert gas systems; instrument and plant/utility air systems; power generation and electrical systems; utility water and other utility systems; security systems; cathodic protection systems; relief device, blowdown, vent, and flare systems; fuel gas systems; spill containment systems; passive protection systems; hazard detection systems; hazard control systems; firewater systems; structural and natural hazard mitigation systems; emergency response systems; and emission control systems.

(6) *Components* means parts of an auxiliary system or LNG facility including piping and valves; process vessels; storage containers; rotating equipment; fired equipment; buildings and structures, including accessways, stairs, ladders, platforms, hoists, and cranes; electrical components; instrumentation and control system components; and safety instrument system components.

(7) *Pipeline facilities* means mainline, lateral, or compressor facilities used to transport gas to or from an LNG terminal.

(8) *Capacity* means the (i) import or export capacity of an LNG terminal and (ii) storage and delivery capacity of interstate LNG plants.

(9) *Footprint* means the area located: (i) within an LNG plant's security systems; and (ii) within the areas protected from natural hazards.

(10) *Design limits* means: (i) the minimum and maximum design flows; (ii) the minimum and maximum liquid design levels and volumes; (iii) the minimum (vacuum) and maximum design pressures; (iv) the minimum design metal temperature and maximum design temperature, (v) the minimum and maximum compositions, and (vi) the maximum structural design loads and criteria of the LNG facilities, auxiliary systems, and components.

(11) *Areas protected from natural hazards* means areas within storm surge barriers and tsunami barriers, or areas at or above the site elevations protected from storm surge levels, tsunami inundation levels, and floodplains at the LNG terminal or plant.

(12) *Security systems* means security enclosures, access controls, security intrusion monitoring and detection systems, and security lighting.

(13) *Upgraded* means providing equal or greater level of safety, security, reliability, operability, efficiency, and environmental protection.

(14) *Modify* means to change the design or operational conditions of components within existing LNG facilities and auxiliary systems, including but not limited to changing process controls, software, setpoints, size/diameter, wall thickness, materials of construction, routing, location, or other process, mechanical, electrical, hazard mitigation, or structural related specifications, designs, or operations.

(15) *Piping and valves* include all types of piping, tubing, flanges, gaskets, fittings, valves, actuators, or other components designed or used to convey, direct, start, or stop fluids within an enclosed system.

(16) *Process vessels* include heat exchangers, columns, separators, and reactors and any other pressure vessel or container designed or used to remove, knockout, separate, distill, combine, heat, cool, react, or change the vapor or liquid fraction, composition, temperature, or other process condition of fluids.

(17) *Storage containers* include atmospheric tanks, low-pressure tanks, pressure vessels, or other containers designed or used as storage for fluids.

(18) *Rotating equipment* includes pumps, compressors, expanders, companders, fans, turbines, internal combustion engines, electrical motors, or other equipment and drivers with rotating or spinning components designed or used to impose or extract work.

(19) *Fired equipment* includes heaters, furnaces, boilers, incinerators, thermal oxidizers, vaporizers, flares, fired-turbines, internal combustion engines, and other equipment designed or used to combust gaseous, liquid, or solid fuel.

(20) *Instrumentation and controls* include sensors, transmitters, signaling, fieldbus, basic process control systems, distributed control systems, supervisory control and data acquisition systems, programmable automation controllers, programmable logic controllers, programmable logic relays, remote terminal units, remote input/output, software, human machine interfaces, historians, network architecture, actuators, control valves, and other integrated components designed or used to measure, monitor, record, and manually or automatically control physical process conditions, such as flow, pressure, temperature, level, and composition.

(21) *Safety instrumented systems* are either: (i) independent safety systems separate from the basic process control systems or (ii) part of integrated control and safety systems, comprising sensors, transmitters, certified safety integrity

level logic solvers, segmented or separated servers in network architecture, actuators, blowdown and emergency shutdown valves with independent or integrated communication networks, software, human machine interfaces, historians, and other independent or integrated components designed or used to depressurize, de-inventory, isolate, shutdown or otherwise reduce the risk of process conditions exceeding the basis of design of the mechanical components and systems that could lead to a loss of containment.

(22) *Delivery point* means a tap and/or metering and appurtenant facilities, such as gas heaters, minor gas conditioning, treatment, odorization, and similar equipment, necessary to enable the blanket authorization holder to deliver gas to any party.

(23) *Receipt point* means a tap and/or metering and appurtenant facilities such as gas heaters, minor gas conditioning, treatment, odorization, and similar equipment, necessary to enable the blanket authorization holder to receive gas from any party.

(24) *Project* means a unit of improvement or construction that is used and useful upon completion.

(25) *Sensitive environmental area* means:

(i) The habitats of species which have been identified as endangered or threatened under the Endangered Species Act (Pub. L. 93–205, as amended) and essential fish habitat as identified under the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801, *et seq.*);

(ii) National or State Forests or Parks;

(iii) Properties listed on, or eligible for inclusion in, the National Register of Historic Places, or the National Register of Natural Landmarks;

(iv) Floodplains and wetlands;

(v) Designated or proposed wilderness areas, national or state wild and scenic rivers, wildlife refuges and management areas and sanctuaries;

(vi) Prime agricultural lands, designated by the Department of Agriculture; or

(vii) Sites which are subject to use by American Indians and other Native Americans for religious purposes.

(26) *Emergency* means a sudden unanticipated loss of gas supply or capacity that requires an immediate restoration of interrupted service for protection of life or health or for maintenance of physical property.

■ 5. Add § 153.103 to read as follows:

§ 153.103 Blanket authorization.

(a) *Effect.* A blanket authorization issued pursuant to this subpart permits

the blanket authorization holder, in accordance with the provisions of this subpart, to engage in any of the activities specified in § 153.108 and § 153.109 (as may be amended from time to time).

(b) *Automatic authorization.* A blanket authorization issued pursuant to this subpart permits the blanket authorization holder to engage in activities described in § 153.108(c) and § 153.109(c) without further Commission approval.

(c) *Prior notice required.* A blanket authorization issued pursuant to this subpart permits the blanket authorization holder to engage in activities described in § 153.108(d) and § 153.109(d), if the requirements of § 153.105 have been fulfilled.

(d) *Landowner and local municipality notification.*

(1) Except as identified in paragraph (d)(3) of this section, no activity described in paragraph (b) of this section is authorized unless the blanket authorization holder notifies all affected landowners, as defined in § 157.6(d)(2), and each local municipality (*i.e.*, the city, town, or similar local political subdivision) in which the blanket activity would occur by certified or first class mail at least 45 days prior to commencing construction or at the time it initiates easement negotiations, whichever is earlier. A landowner or local municipality may waive the 45-day prior notice requirement in writing as long as the notice has been provided. For activity required to restore service in an emergency, the 45-day prior notice period is satisfied in the event a company obtains all necessary easements. The notification shall include at least:

(i) A brief description of the facilities and/or components to be constructed, modified, or replaced;

(ii) The name and phone number of a company representative who is knowledgeable about the project; and

(iii) For landowners, a brief description of the effect the construction activity will have on the landowner's property and a description of the company's environmental complaint resolution procedure that must:

(A) Provide landowners with clear and simple directions for identifying and resolving their environmental mitigation problems and concerns during construction of the project and restoration of the right-of way;

(B) Provide a local or toll-free phone number and the name of a specific person to be contacted by landowners and with responsibility for responding to landowner problems and concerns,

and who will indicate when a landowner should expect a response;

(C) Instruct landowners that if they are not satisfied with the response, they may call the company's Hotline; and

(D) Instruct landowners that, if they are still not satisfied with the response, they may contact the Commission's Landowner Helpline at the current telephone number and email address, which is to be provided in the notification.

(2) For activities described in paragraph (c) of this section, the company shall notify in writing all affected landowners, as defined in § 157.6(d)(2), and each local municipality (*i.e.*, the city, town, or similar local political subdivision) in which the blanket activity would occur by certified or first class mail within at least three business days following the date that a docket number is assigned to the request and at the time it initiates easement negotiations. The notice should include at least:

(i) A brief description of the company and the proposed project, including the facilities and/or components to be constructed, modified, or replaced and the location (including a general location map), the purpose, and the timing of the project;

(ii) For landowners, a brief description of the effect the construction activity will have on the landowner's property and a general description of what the company will need from the landowner if the project is approved, and how the landowner may contact the company, including a local or toll-free phone number and the name of a specific person to contact who is knowledgeable about the project;

(iii) The docket number (if assigned) for the request;

(iv) A general description of the blanket authorization program and procedures, as posted on the Commission's website at the time the notification is prepared, and the link to the information on the Commission's website;

(v) A brief summary of the rights the landowner or local municipality has in Commission proceedings;

(vi) The following paragraph: This project is being proposed under the prior notice requirements of the blanket authorization program administered by the Federal Energy Regulatory Commission. Under the Commission's regulations, you have the right to protest this project within the timeframe required under 18 CFR 153.105(d) in the Commission's notice of the company's filing. If you file a protest, you should include the docket number listed in this letter and provide the specific reasons

for your protest. The protest should be filed with the Secretary of the Federal Energy Regulatory Commission. A copy of the protest should be provided to the company. If you have any questions concerning these procedures you can call the Commission's Office of External Affairs at (202) 208–1088; and

(vii) The description of the company's environmental complaint resolution procedure as described in paragraph (d)(1)(iii) of this section.

(3) *Exceptions.*

(i) No landowner or local municipality notice is required for replacements made to comply with federal regulations, or for safety, environmental, or unplanned maintenance reasons that are not foreseen and that require immediate attention by the blanket authorization holder.

(ii) No landowner or local municipality notice is required for activities that do not involve ground disturbance, increases to operational air and noise emissions, or increases to public safety risks.

(4) If paragraphs (d)(1) or (d)(2) of this section require a blanket authorization holder to reveal Critical Energy Infrastructure Information (CEII), as defined by § 388.113(c) of this chapter, to any person, the blanket authorization holder shall follow the procedures set out in § 157.10(d).

■ 6. Add § 153.104 to read as follows:

§ 153.104 Application procedure.

(a) *Who may apply.* Any LNG terminal authorization holder that has a Commission-approved Emergency Response Plan that includes a cost-sharing plan pursuant to section 3(A) of the Natural Gas Act, any LNG plant certificate holder, or any applicant requesting authorization to construct or operate an LNG plant, may apply for a blanket authorization under this subpart in the manner prescribed in §§ 157.6(a) and 385.2011 of this chapter.

(b) *Hearing procedure.* Upon receiving an application for a blanket authorization under this subpart, the Commission will conduct a hearing pursuant to section 3 or section 7 of the Natural Gas Act and § 157.11 of this chapter.

(c) *Issuance.*

(1) For applicants which hold an LNG terminal authorization, the Commission will issue a blanket authorization to the applicant if doing so will not be inconsistent with the public interest.

(2) For applicants which hold an LNG plant certificate, the Commission will issue a blanket authorization to the applicant if doing so is required by the

present or future public convenience and necessity.

(d) *Application contents.*

Applications for blanket authorizations shall contain:

(1) Information indicating the exact legal name of the applicant; its principal place of business; whether the applicant is an individual, partnership, corporation or otherwise; citation to the proceeding(s) in which the applicant was granted a section 3 authorization or section 7 certificate; the state under the laws of which the applicant is organized or authorized to do business; and the name, title, and mailing address and telephone number of the person or persons to whom communications concerning the application are to be addressed; and

(2) A statement that the applicant will comply with the terms, conditions and procedures specified in this subpart.

■ 7. Add § 153.105 to read as follows:

§ 153.105 Notice procedure.

(a) *Applicability.* No activity described in § 153.108(d) or § 153.109(d), except for activity required to restore service in an emergency, is authorized by a blanket authorization granted under this subpart, unless, prior to undertaking such activity:

(1) The notice requirements have been fulfilled in accordance with the provisions of this section; and

(2) Either

(i) no protest has been filed pursuant to paragraph (e) of this section or,

(ii) if a protest has been filed, it has been withdrawn or dismissed pursuant to paragraph (g) of this section.

(b) *Contents.* For any activity subject to the requirements of this section, the blanket authorization holder must file with the Secretary of the Commission, as prescribed in §§ 157.6(a) and 385.2011 of this chapter, a request for authorization under the notice procedures of this section that contains:

(1) The exact legal name of the blanket authorization holder and mailing address and telephone number of the person or persons to whom communications concerning the request are to be addressed;

(2) The docket number in which its blanket authorization was issued;

(3) Any information required in §§ 153.108 and 153.109 of this chapter for the particular activity;

(4) A verified statement that the proposed activity complies with the requirements of this subpart;

(5) Identities and docket numbers of other applications related to the activity. All related filings must be made within 10 days of the first filing. Otherwise the requests on file will be rejected under

paragraph (c) of this section without prejudice to refiling when all parties are ready to proceed.

(c) *Rejection of request.* The Director of the Office of Energy Projects shall reject within 10 days of the date of filing a request which patently fails to comply with the provisions of paragraph (b) of this section, without prejudice to the blanket authorization holder's refiling a complete request.

(d) *Publication of notice of request.* Unless the request has been rejected pursuant to paragraph (c) of this section, the Secretary of the Commission shall issue a notice of the request within 10 days of the date of the filing, which will then be published in the **Federal Register**. The notice shall designate a deadline for filing protests, or interventions to the request. The deadline shall be 60 days after the date of issuance of the notice of the request for activities described by § 153.108(d)(1) and § 153.109(d), and 90 days after the date of issuance of the notice of the request for activities described by § 153.108(d)(2).

(e) *Protests.*

(1) Any person or the Commission's staff may file a protest prior to the deadline. Copies of the protest must be served on the Secretary of the Commission and the blanket authorization holder.

(2) Protests shall be filed in the following form:

United States of America Before the Federal Energy Regulatory Commission
[Name of company holding the blanket authorization] Docket No. [Include both docket no. of the blanket authorization and the prior notice activity]

Protest to Proposed Blanket Authorization Activity

(Name of Protestor) hereby protests the request filed by (Name of blanket authorization holder) to conduct a (construction of facilities, abandonment, etc.) under § 153._____ of the Commission's regulations. Protestor seeks to have this request processed as a separate application.

(Include a detailed statement of Protestor's interest in the activity and the specific reasons and rationale for the objection and whether the protestor seeks to be an intervenor.)

(f) *Effect of protest.* If a protest is filed in accordance with paragraph (e) of this section, then the blanket authorization holder, the person who filed the protest, any intervenors, and staff may resolve the protest and file a withdrawal of the protest pursuant to paragraph (g) of this section prior to the issuance of a Commission order that would have

otherwise been required in the absence of such withdrawal. Informal settlement conferences may be convened by the Director of the Office of Energy Projects or his designee. If a protest is not withdrawn or dismissed pursuant to paragraph (g) of this section, the activity shall not be deemed authorized by the blanket authorization. Instead, the request filed by the blanket authorization holder shall be treated as an application for section 3 or section 7 authorization for the particular activity. The **Federal Register** notice of the request shall be deemed to be notice of the section 3 or section 7 application sufficient to fulfill the notice requirement of §§ 157.9 and 157.10.

(g) *Withdrawal or dismissal of protests.* The protestor may withdraw a protest prior to a Commission order that would have otherwise been required in the absence of such withdrawal by submitting written notice of withdrawal to the Secretary of the Commission and serving a copy on the blanket authorization holder, any intervenors and any other party requesting service. The withdrawal must state that the blanket authorization holder and the protestor concur in the withdrawal. Within 10 days of the filing of a protest, the Director of the Office of Energy Projects will dismiss that protest if it does not raise a substantive issue and fails to provide any specific detailed reason or rationale for the objection. If a protest is dismissed, the notice requirements of this section will not be fulfilled until the earlier of: (1) a 30 day period following the deadline determined in paragraph (d) of this section has run; or (2) the dismissed protesting party notifying the Secretary of the Commission that its concerns have been resolved.

(h) *Final authorization.*

(1) If no protest is filed within the time allowed by the Secretary, the blanket authorization holder is authorized to conduct the activity under its blanket authorization, effective on the day after time expires for filing protests and interventions unless, during that time, the blanket authorization holder withdraws its request in accordance with § 385.216 of this chapter.

(2) If any protest is filed within the time allowed for protest and interventions and is subsequently withdrawn under paragraph (g) of this section, the blanket authorization holder is authorized to conduct the activity under its blanket authorization, effective upon the day after the withdrawal of all protests, unless the blanket authorization holder withdraws its

request in accordance with § 385.216 of this chapter prior to that date.

■ 8. Add § 153.106 to read as follows:

§ 153.106 Standard conditions.

Any activity authorized under a blanket authorization issued under this subpart is subject to the following conditions:

(a) *Revisions.*

(1) The Commission reserves the right to amend the requirements of this subpart from time to time.

(2) The blanket authorization is not transferable in any manner and shall be effective only so long as the blanket authorization holder continues the activities authorized by the order issuing such authorization and does so in accordance with the provisions of the Natural Gas Act, as well as applicable rules, regulations, and orders of the Commission.

(b) *Environmental compliance.* This paragraph only applies to activities that involve ground disturbance or increases in operational air emissions, operational noise emissions, or public safety risks.

(1) The blanket authorization holder shall adopt the requirements set forth in § 380.15(a) and (b) of this chapter for all activities authorized by the blanket authorization and shall issue the relevant portions thereof to construction personnel, with instructions to use them.

(2) All activities shall be consistent with all applicable law including the provisions of the following statutes and regulations or compliance plans developed to implement these statutes:

(i) Clean Water Act, as amended (33 U.S.C. 1251 *et seq.*) and the National Pollution Discharge Elimination System Program, 40 CFR part 122 *et seq.*;

(ii) Clean Air Act, as amended (42 U.S.C. 1801 *et seq.*) and air quality regulations and state implementation plans adopted pursuant to 40 CFR parts 50–99;

(iii) National Historic Preservation Act of 1966 (16 U.S.C. 470 *et seq.*);

(iv) Archeological and Historic Preservation Act of 1974 (Pub. L. 93–291);

(v) Coastal Zone Management Act of 1972, as amended (16 U.S.C. 1451 *et seq.*);

(vi) Endangered Species Act of 1973, Public Law 93–205, as amended (16 U.S.C. 1531 *et seq.*);

(vii) Executive Order 11988, May 24, 1977 requiring Federal agencies to evaluate the potential effects of any actions it may take on a floodplain;

(viii) Executive Order 11990, May 24, 1977 requiring an evaluation of the potential effects of construction on wetland;

(ix) Wild and Scenic Rivers Act (16 U.S.C. 1274 *et seq.*);

(x) National Wilderness Act (16 U.S.C. 1133 *et seq.*);

(xi) National Parks and Recreation Act of 1978 (16 U.S.C. 1 and 230 *et seq.*);

(xii) Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*);

(xiii) Rivers and Harbors Act (33 U.S.C. 400 *et seq.*);

(xiv) Migratory Bird Treaty Act (16 U.S.C. 703 *et seq.*);

(xv) Fish and Wildlife Coordination Act (16 U.S.C. 661 *et seq.*);

(xvi) Bald and Golden Eagle Protection Act (16 U.S.C. 668 *et seq.*);

(xvii) Marine Protection, Research, and Sanctuaries Act (33 U.S.C. 1401 *et seq.*);

(xviii) Marine Mammal Protection Act (16 U.S.C. 1361 *et seq.*);

(xix) Farmland Protection Policy Act (7 U.S.C. 4201 *et seq.*);

(xx) Pipeline Safety Act (49 U.S.C. 60101 *et seq.*);

(xxi) Ports and Waterways Safety Act (33 U.S.C. 1221 *et seq.*);

(xxii) Marine Transportation Security Act (46 U.S.C. 2101 note and 70101 *et seq.*);

(xxiii) Coast Guard Authorization Act of 2010 (Pub. L. 111–281, 124 Stat. 2905 (Oct. 15, 2010)).

(3) The blanket authorization holder shall be deemed in compliance with:

(i) Paragraph (b)(2)(iii) of this section only if it adheres to the procedures in appendix II of part 157 subpart F of this chapter in which case the Commission finds that there is no effect on any property protected by 16 U.S.C. 470f;

(ii) Paragraph (b)(2)(vi) of this section only if it adheres to the procedures in appendix I of part 157 subpart F of this chapter in which case the Commission finds that endangered species and their critical habitat are protected in accordance with 16 U.S.C. 1536;

(iii) Paragraph (b)(2)(v) of this section only if the appropriate state agency designated to administer the state's coastal zone management plan, prior to construction of the project, waives its right of review or determines that the project complies with the state's coastal zone management plan;

(iv) Paragraphs (b)(2)(i) and (viii) of this section only if it adheres to Commission staff's current "Upland Erosion Control, Revegetation and Maintenance Plan" and "Wetland and Waterbody Construction and Mitigation Procedures" which are available on the Commission internet home page or from the Commission staff, or gets written approval from the staff or the appropriate Federal or state agency for the use of project-specific alternatives to

clearly identified portions of those documents.

(4) Any activity authorized under a blanket authorization shall not have a significant adverse effect on a sensitive environmental area.

(5) Any activity authorized under a blanket authorization that increases operational noise emissions shall not have a significant adverse effect on noise sensitive areas, as follows:

(i) The noise attributable to any new meter station, compressor station, LNG terminal, or LNG plant, or any modification, upgrade, or update thereto, such as from new or modified fired or rotating equipment, must not exceed a day-night noise level (L_{dn}) of 55 dBA at any pre-existing noise-sensitive area (such as schools, hospitals, or residences).

(ii) Fired and rotating equipment and other noise-emitting components installed at a meter station, compressor station, LNG terminal, or LNG plant under this section must be designed to meet the following noise emissions criteria. For each project, the blanket authorization holder must file a full load noise survey with the Secretary within 60 days of placing the equipment in service. If a full load condition noise survey is not possible, the blanket authorization holder must provide an interim survey at the maximum possible load and provide the full load survey within 6 months.

(A) If noise emitted from the existing LNG terminal, LNG plant, meter station, or compressor station at full load exceeds an L_{dn} of 55 dBA at any noise-sensitive area (NSA), or if an addition or modification to an existing LNG terminal, LNG plant, meter station, or compressor station operating at full load at or below an L_{dn} of 55 dBA at NSAs causes overall noise attributable to the facility to exceed an L_{dn} of 55 dBA at an NSA, the blanket authorization holder must come into compliance with an L_{dn} of 55 dBA at NSAs within 1 year of placing the new, replaced, or modified components in service.

(B) If an addition or modification to an existing LNG terminal, LNG plant, meter station, or compressor station operating at full load above an L_{dn} of 55 dBA at NSAs causes overall noise attributable to the terminal, plant, or station to increase at an NSA, the blanket authorization holder must act within 1 year of placing the added or modified facility in service to reduce noise at NSAs to the level that existed prior to the addition or modification.

(C) If the initial noise survey demonstrates a need to take action to mitigate noise, within 60 days of completing such action, the blanket

authorization holder must file a subsequent noise survey with the Secretary demonstrating that each new fired and rotating equipment or other noise-emitting components at the modified meter station, compressor station, LNG terminal, or LNG plant complies with the noise level limits.

(6) Any horizontal directional drilling, pile driving, or drilling of wells which will occur between 10 p.m. and 7 a.m. local time must be conducted with the goal of keeping the perceived noise from the activity at any pre-existing noise-sensitive area (NSA) (such as schools, hospitals, or residences) at or below a day-night level (L_{dn}) of 55 dBA.

(7) Any activity otherwise subject to authorization under § 153.109 shall not be authorized if the activity is located within 0.5 miles of a nuclear power plant which is either operating or under construction, or for which a construction permit has been filed with the Nuclear Regulatory Commission.

(8) The blanket authorization holder shall act as the Commission's non-Federal representative upon acceptance of the blanket authorization for purposes of complying with the Endangered Species Act of 1973.

(9) The blanket authorization holder shall act as the Commission's non-Federal representative upon acceptance of the blanket authorization for purposes of complying with the National Historic Preservation Act of 1966.

(c) *Engineering compliance.*

(1) *Facility Inspections.* Throughout the life of the replacements, modifications, and new components, systems, and facilities authorized under this subpart, the blanket authorization holder and its components, systems, and facilities shall be subject to regular Commission staff technical reviews and site inspections on at least an annual basis for LNG terminals and biennial basis for LNG plants in interstate service, or more frequently as circumstances indicate. Prior to each Commission staff technical review and site inspection, the blanket authorization holder shall respond to any specific data requests, including information relating to possible design and operating conditions that may have been imposed by other agencies or organizations. Up-to-date, detailed piping and instrumentation diagrams reflecting replacements, modifications, and new components, systems, and facilities and other pertinent information not included in the semi-annual reports described below, including events that have taken place since the previously submitted semi-

annual report, shall be submitted as specified in data requests.

(2) *Semi-Annual Report.* Throughout the life of the replacements, modifications and new components, systems, and facilities authorized under this subpart, the blanket authorization holder shall file semi-annual operational reports with the Secretary to identify changes in design and operating conditions; abnormal operating experiences; applicable activities (e.g., ship arrivals, quantity and composition of imported and exported LNG, liquefied and vaporized quantities, trucking quantities, boil off/flash gas quantities); and plant modifications, including future plans and progress thereof. Abnormalities shall include, but shall not be limited to, the following, as applicable:

- (i) unloading/loading/shipping problems;
- (ii) potential hazardous conditions from offsite vessels, transportation activities (e.g., road, rail, air), or facilities adjacent to the plant site;
- (iii) storage container stratification or rollover;
- (iv) geysering;
- (v) higher than predicted boil-off rates in storage containers;
- (vi) storage container pressure excursions (high or low);
- (vii) negative pressure (vacuum) within a storage container;
- (viii) relative movement of storage container inner vessels;
- (ix) cold spots on the storage containers;
- (x) storage container vibrations and/or vibrations in associated cryogenic piping;
- (xi) storage container settlement;
- (xii) pipe movement including spring hanger position indicator(s) outside of normal range;
- (xiii) significant equipment or instrumentation malfunctions or failures;
- (xiv) non-scheduled maintenance or repair (and reasons therefor);
- (xv) leaking or inoperative isolation valves;
- (xvi) hazardous fluid releases;
- (xvii) fires involving hazardous fluids and/or from other sources; and,
- (xiii) adverse weather conditions and the effect on the plant and facilities.

(3) Semi-annual operational reports shall be submitted within 45 days after each period ending June 30 and December 31. In addition to the above items, a section entitled "Significant Plant Modifications Proposed for the Next 12 Months" shall be included in the semi-annual operational reports.

(4) Throughout the life of the replacements, modifications and new

components, systems, and facilities authorized under this subpart, the blanket authorization holder shall notify Commission staff within 24 hours in the event the temperature of any region of an LNG storage container, including any secondary containment and embedded pipe supports, becomes less than the minimum specified operating temperature for the material, and specify procedures for corrective action.

(5) Throughout the life of the replacements, modifications, and new components, systems, and facilities authorized under this subpart, the blanket authorization holder shall report to Commission staff significant non-scheduled events, including safety-related incidents (e.g., LNG, condensate, refrigerant, or natural gas releases; fires; explosions; mechanical failures; unusual over-pressurization; and major injuries) and security-related incidents (e.g., unauthorized attempts to enter site, suspicious activities). If an abnormality is of sufficient magnitude to threaten public or employee safety, cause significant property damage, or interrupt service, notification shall be made immediately, without unduly interfering with any necessary or appropriate emergency repair, alarm, or other emergency procedure. In all instances, notification shall be made to Commission staff within 24 hours. This notification practice shall be incorporated into the LNG plant's Emergency Response Plan.

(6) In the event of an incident, the Director of the Office of Energy Projects has delegated authority to take whatever steps are necessary to ensure operational reliability and to protect human life, health, property, or the environment, including authority to direct the LNG facility to cease operations. Following the initial company notification, Commission staff will determine the need for a separate follow-up report or follow-up discussion in the upcoming semi-annual operational report. All company follow-up reports shall include investigation results and recommendations to minimize a reoccurrence of the incident.

(d) *Commencement.* Any authorized construction shall be completed and made available for service by the blanket authorization holder and any authorized operation, or service, shall be available within five years of the date the activity is authorized pursuant to § 153.105(h). The authorization holder may apply to the Director of the Office of Energy Projects for an extension of this deadline.

(e) *Reports.* The authorization holder shall file reports as required by this subpart.

■ 9. Add § 153.107 to read as follows:

§ 153.107 General reporting requirements.

(a) Throughout the modification, construction, and operational life of each new, replaced, or modified LNG facility, auxiliary system, or components thereof authorized by § 153.108(c) and § 153.109(c), the blanket authorization holder shall file in the semi-annual operational report described in § 153.106(c)(2), or earlier if upon request as part of a planned modification, construction, or operational technical review and inspection. The report must include:

(1) a general description and justification of the replacements, modifications, or new components, systems, or facilities and an explanation of how that modification provides an equal or greater level of environmental protection than the original components, systems, or facilities;

(2) revised or new Process Flow Diagrams, Utility Flow Diagrams, and Heat and Material Balances for any replaced, modified, or new components, systems, or facilities that change or create new process or utility flows, pressures, temperatures, compositions, or other conditions;

(3) revised or new plot plans and unit plot plans that depict the location of any modified or new components, systems, and facilities;

(4) revised or new piping and instrumentation diagrams that depict the integration of any modified or new components, systems, and facilities;

(5) the beginning and completion date of construction of the facilities installed and the date service commenced;

(6) a description of the contacts made, reports produced, and results of consultations which took place to ensure compliance with the Endangered Species Act, the National Historic Preservation Act, and the Coastal Zone Management Act;

(7) a list of all permits or approvals from local, state, Federal, or Native American groups or Indian agencies required prior to and during construction, and the status of each, including the date filed, the date issued, and any known obstacles to approval in accordance with 18 CFR 380.12(o)(13);

(8) a list of all federal, state, and local regulations and requirements that apply to the siting, design, construction, testing, monitoring, operation, and maintenance of the proposed project and an explanation of how the proposed project will comply with the applicable Federal regulations, including codes and standards incorporated by reference into Federal regulations in accordance with 18 CFR 380.12(o)(14);

(9) a list of all codes and standards under which the plant (and marine terminal, if applicable) will be sited, designed, constructed, tested, monitored, operated, and maintained, and any special considerations or safety provisions that were applied to the design of plant components in accordance with 18 CFR 380.12(o)(12);

(10) for activities located at LNG terminals, a letter of concurrence from the Department of War that the proposed activity will have minimal impact on military installations, operations, or training pursuant to the Natural Gas Act;

(11) documentation, including images, that restoration of work areas is progressing appropriately;

(12) a discussion of problems or unusual construction issues, including those identified by affected landowners, and corrective actions taken or planned; and

(13) if applicable, a noise survey verifying compliance with § 157.106(b)(5).

(b) Information filed in paragraphs (a)(2) through (4) meet the definition of CEII, as defined by § 388.113(c) of this chapter, and shall be filed in accordance with § 388.113.

(c) If any of the information provided in paragraphs (a)(1) or (a)(5) through (13) is filed as CEII, as defined by § 388.113(c) of this chapter, or as privileged, pursuant to § 388.112 of this chapter, the blanket authorization holder shall file a public summary of all changes undertaken pursuant to blanket authorization.

■ 10. Add § 153.108 to read as follows:

§ 153.108 LNG facilities, auxiliary systems, and associated components at LNG terminals and LNG plants.

(a) This section applies only to the construction, operation, replacement, and miscellaneous rearrangement of LNG facilities, auxiliary systems, and associated components for blanket authorization holders who operate LNG terminals authorized pursuant to section 3 of the Natural Gas Act or LNG plants certificated pursuant to section 7 of the Natural Gas Act.

(b) This section does not apply to the construction, operation, replacement, and miscellaneous rearrangement of pipeline facilities for blanket authorization holders who operate LNG terminals authorized pursuant to section 3 of the Natural Gas Act governed by § 153.109 or pipeline facilities pursuant to section 7 of the Natural Gas Act governed by 18 CFR part 157.

(c) *Automatic authorization.*

(1) *Abandonment.* Blanket authorization holders may abandon the

following LNG facilities, auxiliary systems, and associated components that do not impact existing customers under contract and do not adversely affect the continued safety, reliability, or environmental protection of the remaining LNG facilities, auxiliary systems, or associated components:

(i) LNG facilities, auxiliary systems, or associated components that are degraded, obsolete, or soon to be obsolete;

(ii) LNG facilities, auxiliary systems, or associated components that are approaching, have reached, or have exceeded their design and service life;

(iii) LNG facilities, auxiliary systems, or associated components that may be unsafe to continue to operate; and

(iv) LNG facilities, auxiliary systems, or associated components that no longer offer services under contract.

(2) *Installation, construction, modification, or replacement.* Blanket authorization holders may install, construct, modify, or replace (in-kind or upgraded) components within existing LNG facilities and auxiliary systems provided that the new facilities will be:

(i) located within the footprint and the same vertical and horizontal extents of the existing facilities previously evaluated and authorized at the LNG terminal or plant by the Commission, or those previously reviewed and approved at the LNG terminal or plant by Commission staff as part of final design modifications;

(ii) spaced to allow for safe maintenance, access, and egress, and not increase confinement and congestion levels beyond those previously evaluated and authorized at the LNG terminal or plant by the Commission, or those previously reviewed and approved at the LNG terminal or plant by Commission staff as part of final design modifications; and

(iii) designed using components of the same (in-kind or upgraded) type as those that have been previously evaluated and authorized at the LNG terminal or plant by the Commission, or as those previously reviewed and approved at the LNG terminal or plant by Commission staff as part of final design modifications.

(3) *Limitations.* The activities authorized by this paragraph must not:

(i) result in an increase (or be associated with an increase) of the authorized capacity of an LNG terminal or plant;

(ii) result in an increase in frequency or size of LNG marine vessels at the LNG terminal beyond that previously evaluated in a U.S. Coast Guard Letter of Recommendation and considered by the Commission;

(iii) result in significant modification to LNG facilities beyond what was previously evaluated by the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration and considered by the Commission;

(iv) extend outside the vertical or horizontal extents of the LNG terminal or plant that were previously evaluated for visual impacts and authorized by the Commission, previously used to notify U.S. Department of Transportation Federal Aviation Administration under 14 CFR part 77, and previously evaluated as a basis for Department of War concurrence under the Natural Gas Act;

(v) result in flows, levels, volumes, pressures, temperatures, compositions, or loads outside any of the design limits of the new, replaced or modified LNG facilities, auxiliary systems, and components and the authorized design limits for the remaining LNG facilities, auxiliary systems, and components;

(vi) locate the LNG facilities and auxiliary systems closer to nuclear power reactor facilities, which are either operating or under construction, or for which a construction permit has been filed with the Nuclear Regulatory Commission, than the distance previously evaluated and considered by the Commission;

(d) *Prior notice.* Subject to the requirements of § 153.105 and appendix I of this subpart, blanket authorization holders are authorized to:

(1) install, construct, modify, or replace (in-kind or upgraded) components within existing LNG facilities and auxiliary systems provided that:

(i) the new components or auxiliary systems will:

(A) be within the existing footprint;

(B) be spaced to allow for safe maintenance, access, and egress, and not increase confinement and congestion levels beyond those previously evaluated and authorized at the LNG terminal or plant by the Commission or those previously reviewed and approved at the LNG terminal or plant by Commission staff as part of final design modifications; and

(C) not have a significant adverse impact to reliability or risks to public safety of the LNG terminal or plant beyond those previously evaluated and authorized by the Commission or those previously reviewed and approved at the LNG terminal or plant by Commission staff as part of final design modifications; and

(ii) any change in flows, levels, volumes, pressures, temperatures, compositions, or loads will be within

the design limits of the new, replaced and modified LNG facilities, auxiliary systems, and components and will be within the authorized design limits of the remaining LNG facilities, auxiliary systems, and components.

(2) expand an authorized LNG terminal or plant by constructing new LNG facilities, auxiliary systems, and components provided that the new facilities, systems, and components will:

(i) be located within the authorized footprint of the LNG terminal or plant or adjacent to the footprint of the LNG terminal or plant and permanently occupy no more than 25 additional acres;

(ii) be located on previously disturbed or developed land or waterways;

(iii) be located within industrial zoned areas or areas without zoning;

(iv) be designed using the same (in-kind or upgraded) LNG facilities and auxiliary systems as those previously evaluated and authorized at the LNG terminal or plant; and

(v) be located in accordance with the following criteria regarding distances from nuclear power reactor facilities that are operating or under construction, or for which a construction permit has been filed with the Nuclear Regulatory Commission:

(A) new or modified LNG containers with LNG storage capacities of 10,000,000 gallons (38,000 cubic meters) or more must be 5 miles or more from nuclear power reactor facilities;

(B) new or modified LNG containers with LNG storage capacities of less than 10,000,000 gallons (38,000 cubic meters) but more than 3,000,000 gallons (11,400 cubic meters) must be 3 miles or more from nuclear power reactor facilities; and

(C) all other new or modified LNG containers, LNG facilities, auxiliary systems, and associated components must be 2 miles or more from nuclear power reactor facilities.

(e) *Contents of request.* In addition to the requirements of § 153.105(b), requests filed for activities described under paragraph (d) of this section shall contain:

(1) A detailed description of the facilities and a description of the purpose of the proposed facilities including their relationship to other existing or planned facilities;

(2)

(i) For activities proposed at LNG terminals authorized under section 3 of the Natural Gas Act, a statement explaining how the proposed project is not inconsistent with the public interest; or

(ii) for activities proposed at LNG plants authorized under section 7 of the

Natural Gas Act, a statement explaining how the public convenience and necessity requires approval of the project including a description of the proposed project's purpose and beneficiaries;

(3) Process Flow Diagrams, Utility Flow Diagrams, and Heat and Material Balances for any replaced, modified, or new components, systems, or facilities that change or create new process or utility flows, pressures, temperatures, compositions, or other conditions in accordance with 18 CFR 380.12(o)(10);

(4) A concise analysis discussing the relevant issues outlined in § 380.12(a)–(n) of this chapter. The analysis must identify the existing environmental conditions and the expected significant impacts that the proposed action, including proposed mitigation measures, will cause to the quality of the human environment, including impacts expected to occur to sensitive environmental areas. The analysis must also include the information described in § 380.12(k) and describe how the proposed action will be made to comply with applicable State Implementation Plans developed under the Clean Air Act, if applicable. The analysis must also include a description of the contacts made, reports produced, and results of consultations which took place to ensure compliance with the Endangered Species Act, National Historic Preservation Act and the Coastal Zone Management Act. Include a copy of the agreements received for compliance with the Endangered Species Act, National Historic Preservation Act, and Coastal Zone Management Act, or if no written concurrence is issued, a description of how the agency relayed its opinion to the company. Describe how drilling for wells and horizontal direction drilling would be designed to meet the goal of limiting the perceived noise at NSAs to an L_{dn} of 55 dBA or what mitigation would be offered to landowners;

(5) For requests filed pursuant to section (d)(2), a description of any zoning for the site of the proposed new facilities;

(6) A commitment to having the Environmental Inspector's report filed every week;

(7) A list of all permits or approvals from local, state, Federal, or Native American groups or Indian agencies required prior to and during construction, and the status of each, including the date filed, the date issued, and any known obstacles to approval in accordance with 18 CFR 380.12(o)(13);

(8) A list of all federal, state, and local regulations and requirements that apply to the siting, design, construction,

testing, monitoring, operation, and maintenance of the proposed project and an explanation of how the proposed project will comply with the applicable Federal regulations, including codes and standards incorporated by reference into Federal regulations in accordance with 18 CFR 380.12(o)(14);

(9) A list of all codes and standards under which the plant (and marine terminal, if applicable) will be sited, designed, constructed, tested, monitored, operated, and maintained, and any special considerations or safety provisions that were applied to the design of plant components in accordance with 18 CFR 380.12(o)(12);

(10) For LNG facilities under the jurisdiction of the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA), a letter stating that the proposed activity complies with the federal siting requirements or that such compliance is not required;

(11) For activities located at LNG terminals, evidence that the blanket authorization holder has submitted a new or updated Letter of Intent and Waterway Suitability Assessment, and received a Letter of Recommendation from the U.S. Coast Guard that the waterway is suitable for any increase in LNG marine vessel traffic frequency or size associated with the proposed activity or a determination that a new or updated Letter of Intent, Waterway Suitability Assessment, or Letter of Recommendation is not required;

(12) For activities that exceed the height requirements in 14 CFR 77, an aeronautical study from the U.S. Department of Transportation's Federal Aviation Administration (FAA) concluding that there is no presumed hazard for the proposed activity and construction thereof. Alternatively, if a determination of no presumed hazard cannot be supplied at the time of filing the prior notice request, the blanket authorization holder shall provide evidence that FAA has been provided with notification in accordance with 14 CFR 77 and informed that it may protest the request within the timeframes described in § 153.105;

(13) For activities located at LNG terminals, a letter of concurrence from the Department of War that the proposed activity will have minimal impact on military installations, operations, or training pursuant to the Natural Gas Act;

(14) For activities located at LNG terminals, any safety advisory report from the state agency designated by the Governor indicating the proposed activity does not involve any state or

local or safety concerns. Alternatively, if a safety advisory report cannot be supplied at the time of filing the prior notice request, the blanket authorization holder shall provide evidence that the state agency designated by the Governor has been provided with notification and that the blanket authorization holder has notified the state agency that it has 30 days to issue a safety report or may protest within the timeframes described in § 153.105;

(15) For activities located at LNG terminals, letters from all relevant state and local emergency response organizations and emergency responders responsible for offsite emergency response in proximity to the LNG terminal or LNG marine vessel transit that confirm either no changes in Emergency Response Plans, including cost sharing plans, are needed or that any changes in Emergency Response Plans, including cost sharing plans, were developed in consultation with them for the proposed activity. Alternatively, if such letters cannot be supplied at the time of filing the prior notice request, the blanket authorization holder shall supply evidence that the emergency response organizations and emergency responders responsible for offsite emergency response in proximity to the LNG terminal or LNG marine vessel transit, have been notified that they may protest within the timeframes described in § 153.105;

(16) A preliminary schedule for when the following engineering information would be filed with the Commission, demonstrating that the proposed activity continues to meet or exceed federal regulations and meet or exceed codes and standards identified in the underlying authorizations for the LNG terminal or plant or approved equivalents. The preliminary schedule should include filing with the Commission all applicable revised or new final engineering information listed below prior to issuance for construction, quality management plans prior to construction, pre-commissioning plans and results prior to commissioning, commissioning plans and procedures prior to commissioning, commissioning test results prior to introduction of hazardous fluids, and performance test plans and results and operating and maintenance plans and procedures prior to commencement of service. The engineering information to be filed, as applicable, must include:

(i) geotechnical investigations and studies;

(ii) natural hazard investigations and studies;

(iii) structural basis of design, drawings, specifications, analyses and calculations;

(iv) internal road vehicle protection (e.g., guard rails, barriers, and bollards) basis of design, drawings, specifications, analyses, and calculations;

(v) security enclosure(s), vehicle barriers, and access controls basis of design, drawings, specifications, analyses, and calculations;

(vi) security monitoring and intrusion detection basis of design, drawings, specifications, analyses, and calculations;

(vii) lighting basis of design, drawings, specifications, analyses, and surveys;

(viii) process flow diagrams and heat and material balances;

(ix) plot plan, unit plot plan, and elevation drawings, or three-dimensional drawings;

(x) piping and instrumentation diagrams;

(xi) car seal and lock philosophies, car seal and lock programs, and lists of car-sealed and locked valves;

(xii) process hazard analysis, including any hazard identification studies, hazard and operability review, layer of protection analyses, and safety integrity level calculations and verification studies;

(xiii) cause-and-effect matrices for process instrumentation, fire and gas detection system, or emergency shutdown system with alarms and shutdown functions, details of the voting and shutdown logic, set points, and test documentation;

(xiv) piping, flange, fitting, valve, and insulation drawings, isometrics, specifications, stress analyses, dynamic pressure surge analyses, acoustical and harmonic vibration analyses, other analyses and calculations, and test documentation;

(xv) process vessel drawings, specifications, stress analyses, calculations, and test documentation;

(xvi) rotating equipment drawings, specifications, stress analyses, dynamic pressure surge analyses, acoustical and harmonic vibration analyses, other analyses and calculations, and test documentation;

(xvii) storage container system drawings, specifications, analyses, calculations, and settlement surveys, and test documentation;

(xviii) fired equipment drawings, specifications, analyses, and calculations, and test documentation;

(xix) electrical single line diagrams, schematics, layout plans, electrical area classification drawings, specifications, datasheets, studies, analyses, calculations, and test documentation;

(xx) instrumentation and control drawings, loop diagrams, specifications, instrumentation lists, safe operating limits (upper and lower), control set points, alarm setpoints, data sheets, analyses, calculations, factory assessment test, site acceptance test, site integration test, and other test documentation;

(xxi) safety instrumented system drawings, loop diagrams, specifications, instrumentation lists, alarm and shutdown setpoints, emergency shutdown valve closure times, analyses, data sheets, calculations, factory assessment test, site acceptance test, site integration test and other test documentation;

(xxii) building drawings, specifications, analyses, ventilation calculations, building siting assessments, analyses, calculations, and test documentation;

(xxiii) pressure and vacuum relief valves basis of design, lists, sizing, capacity, analyses, and calculations;

(xxiv) spill containment system, including downcomers, basis of design, drawings, specifications, analyses, capacity calculations; and test documentation;

(xxv) hazard detection, including emergency shutdown button, layout drawings, lists, specifications, datasheets, voting logic, studies, analyses, calculations, and test documentation;

(xxvi) hazard control, including fixed and wheeled dry-chemical, hand-held fire extinguishers, fixed carbon dioxide systems, fixed clean agent systems, and other suppression systems drawings, specifications, studies, analyses, calculations, and test documentation;

(xxvii) cryogenic spill protection drawings, specifications, analyses, and calculations;

(xxviii) vapor barrier drawings, specifications, analyses, and calculations;

(xxvix) blast and fire wall drawings, specification, analyses, and calculations;

(xxx) passive fire protection drawings, specifications, analyses, and calculations;

(xxxi) firewater equipment, including supplies, storage, pumps, shelters/houses, post indicator valves, sectional valves, firewater monitors, hydrants, hose, water curtains, deluge systems, foam systems, water-mist systems, and sprinkler systems drawings, specifications, analyses, calculations, and test documentation;

(xxxii) quality management system plans, including list of hold points and inspection and test plans, for the owner/operator and engineering, procurement,

and construction contractors and subcontractors;

(xxxiii) clean-out, dry-out, purging, and tightness testing plans;

(xxxiv) pressure/leak procedures and test documentation;

(xxxv) commissioning plans and procedures;

(xxxvi) pre-startup safety procedures and reviews;

(xxxvii) standard operating procedures for startup, shutdown, and cooldown, and test documentation;

(xxxviii) simultaneous operations procedures;

(xxxix) maintenance procedures and manuals, including hot work procedures and permits;

(xl) preventative and predictive maintenance program and test schedules/frequencies, scopes, and documentation;

(xli) offsite contractor procedures;

(xlii) management of change procedures and forms;

(xliii) training procedures and logs;

(xliv) alarm management program and reports;

(xlv) abnormal operating conditions reporting procedures; and

(xlii) Emergency Response Plans, including cost sharing plans.

(17) For activities at LNG plants authorized under section 7 of the Natural Gas Act, the blanket authorization holder must include the information required by § 157.208(c)(6).

(f) *Special conditions for prior notice activities.*

(1) Blanket authorization holders shall not segment, separate, or divide projects in order to meet the acreage limitation set forth in paragraph (d)(2)(i).

(2) Prior to commissioning or introduction of hazardous fluids for prior notice activities, blanket authorization holders shall request and must receive written authorization to proceed from the Director of the Office of Energy Projects, or the Director's designee. Instrumentation and control, hazard detection, hazard control, security and other components, systems, or facilities necessary for the safe and secure introduction of such fluids shall be installed and functional;

(3) Prior to placing prior notice activities in service, blanket authorization holders shall request and must receive written authorization from the Director of Office of Energy Projects, or the Director's designee. Such authorization will only be granted following a determination that the facilities that have been constructed can be expected to operate safely as designed, and the rehabilitation and restoration of areas affected by the project are proceeding satisfactorily;

(4) Within 30 days of placing prior notice activities in service, blanket authorization holders shall file an affirmative statement, certified by a senior company official, confirming that the prior notice activities have been installed in compliance with all applicable conditions, and that continuing activities will continue to be consistent with all applicable conditions; and

(5) For prior notice activities, throughout the planned modification, construction, and operational life of replacements, modifications and new components, systems, and facilities, blanket authorization holders must file revised or new engineering information in accordance with the schedule of filing submitted pursuant to paragraph (e)(16) to demonstrate they meet or exceed federal regulations and meet or exceed codes and standards identified in the underlying authorizations or approved equivalents.

■ 11. Add § 153.109 to read as follows:

§ 153.109 Pipeline facilities at LNG terminals and plants.

(a) This section applies only to the construction, operation, replacement, and miscellaneous rearrangement of pipeline facilities for blanket authorization holders who operate LNG terminals authorized pursuant to section 3 of the Natural Gas Act.

(b) This section does not apply to construction, operation, replacement, and miscellaneous rearrangement of LNG facilities or auxiliary systems for blanket authorization holders that operate LNG terminals authorized pursuant to section 3 of the Natural Gas Act or to blanket authorization holders who operate LNG plants authorized pursuant to section 7 of the Natural Gas Act.

(c) *Automatic Authorization.*

(1) If the project cost does not exceed the cost limitations set forth in column 1 of table 1 to § 157.208(d), or if the project is required to restore service in an emergency, the blanket authorization holder is authorized to make miscellaneous rearrangements, abandon, acquire, construct, modify, replace, or operate any pipeline facility.

(2) The blanket authorization holder may acquire, construct, replace, modify, or operate any receipt or delivery point.

(d) *Prior Notice.* If the project cost is greater than the amount specified in column 1 of table 1 to § 157.208(d), but less than the amount specified in column 2 of table 1 to § 157.208(d), the blanket authorization holder is authorized to make miscellaneous rearrangements, abandon, acquire, construct, modify, replace, or operate

any pipeline facility, subject to the requirements of § 153.105.

(e) In addition to the requirements of § 153.105(c), a request for activities described under paragraph (d) of this section shall contain:

(1) the information required in § 157.208(c)(1) through (5) and (9) through (10); and

(2) a statement explaining how the proposed project is not inconsistent with the public interest.

(f) Blanket authorization holders shall not segment, separate, or divide projects in order to meet the cost limitations set forth in this section.

(g) In the interest of safety and reliability of service, facilities authorized by this section shall not be operated at pressures exceeding the maximum operating pressure set forth in the request. In the event that the blanket authorization holder thereafter wishes to change the maximum operating pressure of facilities constructed under this section, it shall file an appropriate request pursuant to the procedures set forth in § 157.105(b). Such request shall include the reasons for the proposed change. Nothing contained herein authorizes the certificate holder to operate any facility at a pressure above the maximum prescribed by State law, if such law requires a lower pressure than authorized hereby.

(h) If the actual cost of the project exceeds the per-project cost authorized by this section, the blanket authorization holder shall apply to the Director of the Office of Energy Projects for a waiver of those project cost limits.

■ 12. Add Appendix I to Subpart E of Part 153.

Appendix I—Management of Change for Significant Adverse Impacts on Reliability or Public Safety

For activities authorized by 18 CFR 153.108(d), blanket authorization holders must provide management of change (MOC) documentation of the modification that impacts the engineering information in 18 CFR 153.108(e)(16). The MOC documentation shall verify that the following layers of

protection provide an equal or greater level of protection as those previously evaluated and authorized at the LNG terminal or plant by the Commission, or as those previously reviewed and approved at the LNG terminal or plant by Commission staff as part of final design:

(a) design of basic process control systems (BPCS), safety instrumented systems (SIS), or applicable instrumentation and control systems;

(b) design and sizing scenarios for pressure and vacuum relief devices, including flare and vent systems;

(c) mechanical designs of components including fluid velocity, dynamic hydraulic surge from valve closures and pumps as well as flow and acoustic induced vibrations;

(d) minimum specification for design metal temperature (MDMT), maximum design temperature (MDT), maximum design pressures (MDP), maximum allowable operating pressure (MAOP), maximum allowable working pressure (MAWP) of components, and corrosion allowances;

(e) design and sizing for spill containment and impoundment systems;

(f) spacing and plant layout of LNG facilities and auxiliary systems;

(g) design of ignition controls including electrical area classification and building ventilation systems;

(h) design of hazard detection systems;

(i) design of emergency shutdown systems, and depressurization or blowdown systems;

(j) design of hazard control systems including layout and travel distance for portable extinguishers;

(k) design to mitigate impacts of cryogenic spills, overpressures, projectiles, fires, or other accidental or intentional external impacts that could increase risk to safety;

(l) design and location of cryogenic spill protection, vapor barriers, blast walls, blast resistant buildings or structures, fire walls, radiant heat shields, passive fire protection systems, or other passive protection systems to prevent cascading damage;

(m) design of firewater systems including firewater location, design densities, capacity, and coverage;

(n) design of structural components including any increases in loading from natural hazards and any larger LNG marine vessels;

(o) scalable procedures in Emergency Response Plans; and

(p) any other studies and/or reports applicable to the modifications.

PART 375—THE COMMISSION

■ 1. The Authority for this section continues to read:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352.

■ 2. Revise § 375.308 to read as follows:

§ 375.308 Delegations to the Director of the Office of Energy Projects.

* * * * *

(v) * * *

(6) To dismiss any protest to prior notice filings made pursuant to §§ 153.105 or 157.205 of this chapter and involving pipeline facilities or LNG facilities and auxiliary systems that does not raise a substantive issue and fails to provide any specific detailed reason or rationale for the objection;

* * *

(8) Applications for blanket certificates of public convenience and necessity pursuant to subpart F of part 157 of this chapter, including waiver of project cost limitations in §§ 157.208 and 157.215 of this chapter; applications for blanket certificates of public convenience and necessity or blanket authorizations pursuant to subpart E of part 153 of this chapter, including waiver of project cost limitations in § 153.109; and the convening of informal conferences during the 30-day reconciliation period pursuant to the procedures in §§ 153.105(f) and 157.205(f).

(w) * * *

(5) Requests for waiver of the landowner notification and local municipality notification requirements in § 153.103(d) or landowner notification requirements in § 157.203(d) of this chapter.

(x) * * *

(5) To reject requests which patently fail to comply with the provisions of §§ 153.105(b) or 157.205(b) of this chapter;

* * *

* * * * *

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UNITED STATES OF AMERICA
FEDERAL ENERGY REGULATORY COMMISSION

Authorizations for Certain Activities at Liquefied
Natural Gas Plants

Docket No. RM26-2-001

(Issued October 15, 2026)

CHANG, Commissioner, *concurring*:

1. In today's order, the Commission proposes to revise its regulations to establish a new blanket certificate program to authorize certain activities at liquified natural gas (LNG) facilities without case-specific authorizations. Similar to the structure of the pipeline blanket program,¹ the Commission proposes a tiered approach, in which activities may be eligible for automatic or 60- or 90-day prior notice authorization. The three tiers intend to reflect a range of projects with different levels of complexity, design modifications, and environmental and safety impacts. I write separately to draw particular attention to the class and scope of activities proposed under the 90-day prior notice procedures and request input from stakeholders regarding the appropriate eligibility conditions and environmental protection safeguards for that proposal.
2. Since 1982, the Commission has operated a blanket program for interstate gas pipelines to undertake certain well-understood activities without case-specific authorizations. The Commission has twice declined to extend the program to include LNG facilities, finding that, at the time, LNG plants were not within the class of minor, well-understood, routine activities intended for the program. However, given the expertise that the Commission has developed on this topic over the last decade, I support the proposal to extend this effort to the LNG authorization process via the development of a new blanket program and to create parity with how gas pipelines are evaluated.
3. As the new blanket program is developed, it is essential that the Commission properly tailor the program to both meet our statutory requirements and provide legal durability and permitting certainty for the natural gas industry. Achieving these objectives requires that the program captures the appropriate types of activities without being overly broad. The program's success will depend on our ability to clearly define the types of activities that are suitable for *ex ante* blanket authorization—namely, activities that are generally well-understood and have minimal impacts on their surroundings. In contrast, a program without sufficient bounds will likely invite protests or legal challenges. The program will not succeed in its intended outcome if every project is protested and thus made ineligible under the blanket.

¹ 18 CFR pt. 157, subpart F (2025).

4. The Notice of Proposed Rulemaking (NOPR) includes a reasonable list of activities proposed to be eligible for automatic and 60-day prior notice authorization, as supported by the record compiled through the Notice of Inquiry. The information about the project site and facility design collected and reviewed during the original authorization should be sufficient to understand the impacts of activities that will not expand the project footprint or make only minor modifications to the facilities. However, the Commission needs more information to understand whether we have set the appropriate limits for projects that fall under the 90-day prior notice category, namely those seeking to expand beyond their original facilities' footprint.

5. Under the proposed rule, projects that qualify for the 90-day prior notice category will be subject to three conditions: (1) expansion outside of the original facility's footprint must occupy less than 25 acres of adjacent land or water that has been previously disturbed or developed; (2) expansion outside of the original footprint must comply with all environmental and engineering conditions in the project's existing authorization; and (3) the facilities must be of the same type as those previously considered and analyzed in the underlying authorization.² The NOPR does not include a cost limit as a qualifying condition, finding that, unlike the pipeline blanket program, project cost is not an appropriate proxy for level of impact for LNG projects. Instead, we propose to use size of the expansion as a measure to help ensure that projects will not have a significant impact on public safety or the environment.

6. I am concerned that we do not yet have enough information in the record to justify the selection of a 25-acre limit as a proxy for minimal impact of a proposed project. I understand that a strict non-expansion policy may create additional safety concerns if applicants are incentivized to propose artificially congested development. However, as acknowledged in the order, an additional 25 acres could allow for the construction of projects as large as an additional liquefaction train or five combined-cycle power generation facilities.³ These kinds of large projects have the potential to create substantial new environmental and safety impacts despite being conceptually well-understood. Thus, qualifying such expansion activities raises questions as to whether using size of adjacent land (or water) as a limit could lead to the inclusion of projects larger than what is legally justifiable for a blanket program.

7. The proposed rule asks stakeholders to provide comment on whether 25 acres beyond plant footprint is an appropriate acreage limitation, and whether the Commission should consider any additional limits on eligibility beyond the three conditions. When evaluating project applications, the Commission must fulfill certain responsibilities under a number of environmental statutes including the National Environmental Policy Act, the Clean Air Act, the Clean Water Act, and the Endangered Species Act. These statutes

² NOPR at P 56.

³ *Id.* P 61.

require detailed analysis of impacts of the project within a certain proposed footprint, but not necessarily the adjacent land and waterways. Under the proposed 90-day prior notice authorization, projects could expand into areas that have not been previously analyzed, even if they do not provide a new or updated environmental review process. I am not yet convinced that allowing project expansions onto a 25-acre adjacent space with the information collected in the 90-day prior notice blanket program will be sufficient to guarantee our compliance with the Commission's statutory obligations. Thus, I request further comment on the following:

Q1: Should the project applicant be required to demonstrate affirmatively that facilities constructed in areas outside of the existing footprint that have not been previously studied will not have a significant environmental impact?

8. Further, the proposed rule does not preclude applicants from seeking multiple—and potentially even an *unlimited* number of—25-acre expansions beyond their original footprint. Though the proposed regulations include language prohibiting blanket authorization holders from segmenting projects as a means of complying with the acreage limitation,⁴ they do not limit the number of times expansions could be permitted over the lifetime of the facility, nor do they state a minimum length of time required between actions. A project with enough adjacent land that had previously been disturbed or developed could, in theory, double in size—or more—without requiring additional environmental analysis from the Commission. Without a limit on the *total* amount of development that could occur outside of the authorized footprint of an existing facility or a facility under development, I am concerned about the Commission's ability to fulfill its statutory duties. Thus, I request stakeholders to submit further comments on the following:

Q2: Should the Commission establish: (1) an upper limit on the number of expansions beyond the project footprint allowed under a single blanket authorization, either in total size or in number of expansion projects; and/or (2) a minimum time period between successive requests?

9. Given these concerns, I encourage stakeholders to help the Commission build a robust record on the proposed 90-day prior authorization category and its specific eligibility conditions. Ultimately, I believe the Commission can establish a blanket program that accomplishes its goal of increased efficiency while simultaneously complying with its statutory obligations. I look forward to reviewing the expanded record to assess how best to achieve both objectives.

⁴ Section 153.108(f)(1) of the proposed regulations.

For these reasons, I respectfully concur.

A handwritten signature in black ink, appearing to read "Judy Chang", with a long horizontal flourish extending to the right.

Judy W. Chang
Commissioner

[FR Doc. 2026-21443 Filed 10-19-26; 8:45 am]

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