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

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

OFFICE OF GOVERNMENT ETHICS

5 CFR Parts 2634 and 2635

RIN [INSERT]

Executive Branch Financial Disclosure and Standards of Ethical Conduct Regulations

AGENCY: Office of Government Ethics.

ACTION: Final rule; technical amendments.

SUMMARY: The U.S. Office of Government Ethics (OGE) is updating its executive branch regulation on financial disclosure to reflect the retroactive statutory increase of the reporting thresholds for gifts and travel reimbursements. OGE is also updating the executive branchwide standards of ethical conduct regulation to raise the widely attended gatherings nonsponsor gifts exception dollar ceiling tied to these thresholds. This latter change is not retroactive.

DATES:

Effective date: This final rule is effective October 28, 2026.

Applicability date: The amendments to 5 CFR 2634.304 and 2634.907 are applicable as of January 1, 2026.

FOR FURTHER INFORMATION CONTACT: Christie Chung, Assistant Counsel, or Marjorie Levine, Assistant Counsel; Telephone: 202-482-9300.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Office of Government Ethics (OGE) is amending pertinent sections of its executive branchwide ethics regulations on financial disclosure and standards of ethical conduct, as codified at 5 CFR parts 2634 and 2635, in order to update the thresholds for gifts and travel reimbursements, as well as the widely attended gatherings nonsponsor gifts exception dollar ceiling.

Increased Gifts and Travel Reimbursements Reporting Thresholds

First, OGE is revising its executive branch financial disclosure regulation at 5 CFR part 2634 to reflect the increased reporting thresholds for gifts, reimbursements, and travel expenses for both the public and confidential executive branch financial disclosure systems. The increased thresholds are applicable as of January 1, 2026. These increases conform to the statutorily mandated public disclosure reporting thresholds under the Ethics in Government Act as amended, 5 U.S.C. 13104(a)(2)(A) and (B), and are extended to confidential disclosure reporting by OGE's regulation. Under the Ethics in Government Act, the gifts and travel reimbursements reporting thresholds are tied to the dollar amount for the "minimal value" threshold for foreign gifts as the General Services Administration (GSA) periodically redefines it.

GSA raised the "minimal value" amount under the Foreign Gifts and Decorations Act, 5 U.S.C. 7342, to \$525 for the three-year period 2026–2028 (from the prior level of \$480) in a December 29, 2025, Federal Management Regulation Bulletin. See Gen. Servs. Admin., GSA Bull. FMR B–2025–01, Foreign Gifts and Decorations Minimal Value (2025) (revising, effective January 1, 2026, the foreign gifts minimal value definition as codified at 41 CFR 102–42.10).

Accordingly, applicable as of January 1, 2026, OGE is increasing the thresholds for reporting of gifts and travel reimbursements from any one source in 5 CFR 2634.304 and 2634.907(g). The thresholds have been raised to "more than \$525" for the gifts and travel reimbursements aggregation thresholds and "\$210 or less" for the de minimis exception for gifts and travel reimbursements that do not have to be aggregated. As noted, these regulatory increases implement the underlying statutory increases effective January 1, 2026. OGE is also updating the examples following those sections, including appropriate adjustments to gift values.

OGE will continue to adjust the gifts and travel reimbursements reporting thresholds in its part 2634 regulation in the future as needed in light of GSA's redefinition of "minimal value" every three years for foreign gifts purposes.

See OGE's prior three-year adjustment of those regulatory reporting thresholds, as published at 88 FR 37753 (June 9, 2023) (for 2023–2025, the aggregate reporting thresholds were more than \$480, with a \$192 or less de minimis exception).

Increased Dollar Ceiling for the Exception for Nonsponsor Gifts of Free Attendance at Widely Attended Gatherings

OGE is also increasing the exception ceiling for nonsponsor gifts of free attendance at widely attended gatherings from \$480 to \$525 in the executive branch standards of ethical conduct regulation, as codified at 5 CFR 2635.204(g)(3) (and as illustrated in the examples following paragraph (g)). This separate regulatory change is effective upon publication in the **Federal Register**, on October 28, 2026. As OGE noted in the preambles to the proposed and final rules on such nonsponsor gifts, that ceiling is tied to the financial disclosure gifts reporting threshold. See 60 FR 31415 (June 15, 1995) and 61 FR 42965 (Aug. 20, 1996). Thus, OGE is again increasing the nonsponsor gift ceiling to match the further increase in the gifts and travel reimbursements reporting thresholds described above. The nonsponsor gift ceiling was last raised in June 2023. See 88 FR 37753 (June 9, 2023). The other requirements for acceptance of such nonsponsor gifts, including an agency interest determination and expected attendance by more than 100 persons, remain unchanged.

II. Other Technical Changes

Designation of Notes and Examples

OGE is designating various notes and examples in §§ 2634.304 and 2634.907. The designation of those notes and examples are technical amendments involving no substantive changes to the regulations.

III. Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(A) and (B), as Acting Director of the Office of Government Ethics, I find that good cause exists for waiving the general notice of proposed rulemaking and public comment procedures as to these technical amendments. The notice and comment procedures are being waived because these amendments concern

matters of agency organization, procedure, and practice. Further, notice and comment is unnecessary because these are technical amendments unlikely to be of significant interest to the public. Finally, it is also in the public interest that the accurate and up-to-date information be contained in the affected sections of OGE's regulations as soon as possible. The increase in the reporting thresholds for gifts and reimbursements is based on a statutory formula and lessens the reporting burden. Therefore, that regulatory revision is retroactively applicable as of January 1, 2026, when the change became effective under the Ethics in Government Act. For the reasons described above, this rule may take immediate effect pursuant to 5 U.S.C. 553(d)(1) and (d)(3).

Regulatory Flexibility Act

As the Acting Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this final rule would not have a significant economic impact on a substantial number of small entities because it primarily affects current Federal executive branch employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain information collection requirements that require approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), this final rule would not significantly or uniquely affect small governments and will not result in increased expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (as adjusted for inflation) in any one year.

Congressional Review Act

The Office of Information and Regulatory Affairs has found that this amendatory rulemaking does not meet the criteria for a major rule under the Congressional Review Act (5 U.S.C. 804(2)). The Office of Government Ethics will submit a report thereon to the U.S. Senate, House of Representatives and Government Accountability Office in accordance with that law at the same time this rulemaking document is sent to the Office of the Federal Register for publication in the **Federal Register**.

Executive Order 13563 and Executive Order 12866

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select the regulatory approaches that maximize net benefits (including economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. In promulgating this rulemaking, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in Executive Orders 12866 and 13563. The rule has not been reviewed by the Office of Management and Budget because it is not a significant regulatory action for the purposes of Executive Order 12866.

Executive Order 12988

As Acting Director of the Office of Government Ethics, I have reviewed this rule in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects

5 CFR Part 2634

Certificates of divestiture, Conflict of interests, Government employees, Penalties, Reporting and recordkeeping requirements, Trusts and trustees.

5 CFR Part 2635

Conflict of interests, Executive branch standards of ethical conduct, Government employees.

Approved: October 26, 2026.

Keith Sonderling,

Acting Director, U.S. Office of Government Ethics.

For the reasons set forth in the preamble, the U.S. Office of Government Ethics amends 5 CFR parts 2634 and 2635 as follows:

PART 2634—EXECUTIVE BRANCH FINANCIAL DISCLOSURE, QUALIFIED TRUSTS, AND CERTIFICATES OF DIVESTITURE

■ 1. The authority citation for part 2634 continues to read as follows:

Authority: 5 U.S.C. ch. 131; 26 U.S.C. 1043; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note, as amended by sec. 31001, Pub. L. 104–134, 110 Stat. 1321 and sec. 701, Pub. L. 114–74; Pub. L. 112–105, 126 Stat. 291; E.O. 12674, 54 FR 15159, 3 CFR, 1989

Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 2. Amend § 2634.304 by:

- a. Revising paragraphs (a), (b), (d), and examples 1 through 3 following paragraph (d);
- b. Designating the example following paragraph (e) as Example 1 to paragraph (e); and
- c. Designating the example following paragraph (f)(1) as Example 1 to paragraph (f)(1) and revising the newly designated example.

The revisions read as follows:

§ 2634.304 Gifts and reimbursements.

(a) *Gifts.* Except reports required under § 2634.201(f) and as indicated in § 2634.310(b), each financial disclosure report filed pursuant to this subpart must contain the identity of the source, a brief description, and the value of all gifts aggregating more than \$525 in value which are received by the filer during the reporting period from any one source. For in-kind travel-related gifts, include a travel itinerary, dates, and nature of expenses provided.

Note 1 to paragraph (a): Under the Ethics in Government Act, 5 U.S.C. 13104(a)(2)(A) and (B), the reporting thresholds for gifts, reimbursements, and travel expenses are tied to the dollar amount for the “minimal value” threshold for foreign gifts established by the Foreign Gifts and Decorations Act, 5 U.S.C. 7342(a)(5). The General Services Administration (GSA), in consultation with the Secretary of State, redefines the value every 3 years. As of 2026, the amount was set at \$525. In paragraph (d) of this section, the Office of Government Ethics sets the aggregation exception amount and redefines the value every 3 years. As of 2026, the amount was set at \$210. The Office of Government Ethics will update this part in 2029 and every three years thereafter to reflect the new amounts.

(b) *Reimbursements.* Except as indicated in §§ 2634.309 and 2634.310(b), each financial disclosure report filed pursuant to this subpart must contain the identity of the source, a brief description (including a travel itinerary, dates, and the nature of expenses provided), and the value of any travel-related reimbursements aggregating more than \$525 in value, which are received by the filer during the reporting period from any one source. The filer is not required to report travel reimbursements received from the filer's non-Federal employer.

* * * * *

(d) *Aggregation exception.* Any gift or reimbursement with a fair market value of \$210 or less need not be aggregated for purposes of the reporting rules of this section. However, the acceptance of gifts, whether or not reportable, is subject to the restrictions imposed by

Executive Order 12674, as modified by Executive Order 12731, and the implementing regulations on standards of ethical conduct.

Example 1: An official accepts a print, a pen and pencil set, and a letter opener from a community service organization he has worked with solely in his private capacity. He determines, in accordance with paragraph (e) of this section, that these gifts are valued as follows: Gift 1—Print: \$310; Gift 2—Pen and pencil set: \$225; Gift 3—Letter opener: \$20. The official must disclose Gifts 1 and 2, since together they aggregate more than \$525 in value from the same source. Gift 3 need not be aggregated, because its value does not exceed \$210.

Example 2: An official receives the following gifts from a single source: 1. Dinner for two at a local restaurant—\$200. 2. Round-trip taxi fare to meet donor at the restaurant—\$25. 3. Dinner at donor's city residence—(value uncertain). 4. Round-trip airline transportation and hotel accommodations to visit Epcot Center in Florida—\$600. 5. Weekend at donor's country home, including duck hunting and tennis match—(value uncertain). Based on the minimal value threshold established as of 2026, the official need only disclose Gift 4. Gift 1 falls within the exclusion in § 2634.105(h)(4) for food and beverages not consumed in connection with a gift of overnight lodging. Gifts 3 and 5 need not be disclosed because they fall within the exception for personal hospitality of an individual. Gift 2 need not be aggregated and reported, because its value does not exceed \$210.

Example 3: A non-Federal organization asks an official to speak at an out-of-town meeting on a matter that is unrelated to her official duties and her agency. She accepts the invitation and travels on her own time to the event. The round-trip airfare costs \$600. Based on the minimal value threshold established as of 2026, the official must disclose the value of the plane ticket whether the organization pays for the ticket directly or reimburses her for her purchase of the ticket.

* * * * *

(f) * * *
(1) * * *

Example 1 to paragraph (f)(1): The Secretary of Education and her spouse receive the following two wedding gifts: (A) A crystal decanter valued at \$540 from the Secretary's former college roommate and lifelong friend, who is a real estate broker in Wyoming; and (B) A gift of a print valued at \$560 from a business partner of the spouse, who owns a catering company. Under these

circumstances, the Director of OGE may grant a request for a waiver of the requirement to report on a public financial disclosure report each of these gifts.

* * * * *

- 3. Amend § 2634.907 by:
 - a. Designating the note to paragraph (b)(2) as Note 1 to paragraph (b)(2);
 - b. Designating the example to paragraphs (b)(1) and (b)(3) as Example 1 to paragraphs (b)(1) and (b)(3);
 - c. Designating the note to paragraphs (c)(1) and (c)(2) as Note 2 to paragraphs (c)(1) and (c)(2);
 - d. Designating the note to paragraphs (c)(3)(vii) through (ix) as Note 3 to paragraphs (c)(3)(vii) through (ix);
 - e. Designating examples 1 and 2 following paragraph (c) as Examples 1 and 2 to paragraph (c);
 - f. Designating the example following paragraph (d) as Example 1 to paragraph (d);
 - g. Designating examples 1 through 8 following paragraph (e) as Examples 1 through 8 to paragraph (e);
 - h. Designating the note to paragraph (f)(4) as Note 4 to paragraph (f)(4);
 - i. Designating examples 1 through 3 following paragraph (f) as Examples 1 through 3 to paragraph (f);
 - j. Revising paragraphs (g)(1) and (g)(2);
 - k. Designating the note to paragraph (g)(2) as Note 5 to paragraph (g)(2) and revising the newly designated note;
 - l. Revising Example 1 to paragraph (g);
 - m. Designating the example to paragraph (h)(1) as Example 1 to paragraph (h)(1);
 - n. Designating the example following paragraph (h)(5) as Example 1 to paragraph (h)(5);
 - o. Designating the note to paragraph (h)(6) as Note 6 to paragraph (h)(6);
 - p. Designating the example following paragraph (h)(6) as Example 1 to paragraph (h)(6);
 - q. Designating the note to paragraph (i)(1) as Note 7 to paragraph (i)(1); and
 - r. Designating the note to paragraph (i)(3) as Note 8 to paragraph (i)(3).

The revisions read as follows:

§ 2634.907 Report contents.

* * * * *

(1) *Disclosure of Gifts and Travel Reimbursements.* Each annual financial disclosure report filed pursuant to this subpart must contain a brief description of all gifts and travel reimbursements aggregating more than \$525 in value which are received by the filer during the reporting period from any one source, as well as the identity of the source. For travel-related items, the report must include a travel itinerary,

the dates, and the nature of expenses provided. Special government employees are not required to report the travel reimbursements received from their non-Federal employers.

(2) *Aggregation exception.* Any gift or travel reimbursement with a fair market value of \$210 or less need not be aggregated for purposes of the reporting rules of this section. However, the acceptance of gifts, whether or not reportable, is subject to the restrictions imposed by Executive Order 12674, as modified by Executive Order 12731, and the implementing regulations on standards of ethical conduct.

Note 5 to paragraph (g)(2): The Office of Government Ethics sets these amounts every 3 years using the same disclosure thresholds as those for public financial disclosure filers. As of 2026, the reporting thresholds were set at \$525 and the aggregation threshold was set at \$210. The Office of Government Ethics will update this part in 2029 and every three years thereafter to reflect the new amounts.

* * * * *

(5) * * *

Example 1 to paragraph (g): A filer accepts a laptop bag, a t-shirt, and a cell phone from a community service organization he has worked with solely in his private capacity. He determines that the value of these gifts is: Gift 1—Laptop bag: \$230; Gift 2—T-shirt: \$20; Gift 3—Cell phone: \$340. The filer must disclose Gift 1 and Gift 3 because, together, they aggregate more than \$525 in value from the same source. He need not aggregate or report Gift 2 because the gift's value does not exceed \$210.

* * * * *

PART 2635—STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH

■ 4. The authority citation for part 2635 continues to read as follows:

Authority: 5 U.S.C. 7301, 7351, 7353; 5 U.S.C. ch. 131; E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

■ 5. Amend § 2635.204 by revising paragraph (g)(3)(iv) and examples 1 and 4 to paragraph (g) to read as follows:

§ 2635.204 Exceptions to the prohibition for acceptance of certain gifts.

* * * * *

(g) * * *
(3) * * *

(iv) If a person other than the sponsor of the event invites or designates the employee as the recipient of the gift of free attendance and bears the cost of that gift, the event is expected to be attended by more than 100 persons, and

the value of the gift of free attendance does not exceed \$525.

* * * * *

Example 1 to paragraph (g): An aerospace industry association that is a prohibited source sponsors an industry-wide, two-day seminar for which it charges a fee of \$800 and anticipates attendance of approximately 400. An Air Force contractor pays \$4,000 to the association so that the association can extend free invitations to five Air Force officials designated by the contractor. The Air Force officials may not accept the gifts of free attendance because the contractor, rather than the association, provided the cost of their attendance; the contractor designated the specific employees to receive the gift of free attendance; and the value of the gift exceeds \$525 per employee.

* * * * *

Example 4 to paragraph (g): An employee of the Department of Transportation is invited by a news organization to an annual press dinner sponsored by an association of press organizations. Tickets for the event cost \$525 per person and attendance is limited to 400 representatives of press organizations and their guests. If the employee's attendance is determined to be in the interest of the agency and the agency designee provides a written authorization, the employee may accept the invitation from the news organization because more than 100 persons will attend and the cost of the ticket does not exceed \$525. However, if the invitation were extended to the employee and an accompanying guest, the employee's guest could not be authorized to attend for free because the market value of the gift of free attendance would exceed \$525.

* * * * *

[FR Doc. 2026-21997 Filed 10-27-26; 8:45 am]

BILLING CODE 6345-04-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2026-5064; Airspace
Docket No. 25-ANM-134]

RIN 2120-AA66

Modification of Class E Airspace, Samaritan North Lincoln Hospital Heliport, Lincoln City, OR

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace extending upward from 700 feet above the surface at Samaritan North Lincoln Hospital Heliport, Lincoln City, OR. This action supports the safety and management of instrument flight rules (IFR) operations at the heliport.

DATES: Effective date 0901 UTC, December 24, 2026. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

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

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

FOR FURTHER INFORMATION CONTACT: Bryantjay T. Toves, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231-3465.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies Class E airspace to support IFR operations at Samaritan North Lincoln Hospital Heliport, Lincoln City, OR.

History

The FAA published an NPRM for Docket No. FAA-2026-5064 in the **Federal Register** (91 FR 47156; July 28, 2026), modifying the Class E airspace area at Samaritan North Lincoln Hospital Heliport, Lincoln City, OR. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. The FAA received three comments and provides the following responses.

One comment opposed the modification on the basis that it converts uncontrolled airspace to controlled airspace to support private instrument procedures, benefiting commercial enterprises over general aviation. The commenter requested that the FAA "reconsider or narrow this amendment". Although FAA attempts to preserve navigable airspace to the maximum extent possible, its internal policies require it to designate Class E airspace to accommodate arriving IFR operations.

Another comment suggested an administrative correction to the city name to read, "Lincoln City, OR." The FAA has made that correction.

The final comment was in support of the modification, but requested additional information regarding the FAA's compliance with the National Environmental Policy Act, which is also discussed in the "Environmental Review" section of this document. However, in response to this commenter's questions, the FAA determined that this action qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) and in accordance with FAA Order 1050.1G, "FAA National Environmental Policy Act Implementing Procedures," paragraph B-2.5.a, which applies to "[r]ulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points". In compliance with FAA Order 1050.1G, the FAA reviewed this action for factors and circumstances in which a normally categorically-excluded action may have a significant environmental impact requiring further analysis. It determined that no such extraordinary circumstances exist. The FAA also assessed the potential for impacts to coastal areas or protected-species habitat and determined the impacts would be negligible or non-existent. The FAA also assessed the need for coordination under the Coastal Zone Management Act and found that no such coordination is required. This is an air traffic action, which does not involve land acquisition, physical

ground disturbance, construction, excavation, development activities, or discharges to water bodies.

Incorporation by Reference

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the current version of that order, FAA Order JO 7400.11M, dated July 30, 2026, and effective September 15, 2026. These amendments will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11M, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

The Rule

This action amends 14 CFR part 71 by modifying a Class E airspace area extending upward from 700 feet above the surface at the Samaritan North Lincoln Hospital Heliport, Lincoln City, OR, to contain private-use special instrument flight procedures in support of passenger shuttle, medevac, and cargo operations.

The Class E airspace area for the Samaritan North Lincoln Hospital Heliport is modified to cover an area within a 4.7-mile radius of the heliport, excluding the airspace east of longitude line 123°55'51" W. It includes an extension oriented from the heliport's 291° bearing, expanding 1.2 miles either side extending to the heliport's 6.3-mile radius. This was created to appropriately contain aircraft the COPTER Area Navigation (RNAV) (Global Positioning System [GPS]) 09 approach and the COPTER RNAV (GPS) 036 approach procedures. Furthermore, this airspace area supports instrument arrival operations by providing controlled airspace area as aircraft descending below 1,500 feet above the surface and supports procedural containment during the instrument approach procedure's missed approach segment until the aircraft reaches 1,200 feet above the surface.

The Class E airspace area supports IFR operations as they depart the heliport on the LMPRY ONE DEPARTURE (RNAV) or the WNONA ONE DEPARTURE (RNAV) until the aircraft reaches 1,200 feet above the surface.

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.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) and in accordance with FAA Order 1050.1G, "FAA National Environmental Policy Act Implementing Procedures," paragraph B-2.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11M, Airspace Designations and Reporting Points, dated July 30, 2026, and effective September 15, 2026, is amended as follows:

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

* * * * *

ANM OR E5 Lincoln City, OR [Amended]

Samaritan North Lincoln Hospital Heliport, OR
(Lat. 44°59'11" N, long. 123°59'39" W)

That airspace extending upward from 700 feet above the surface within a 4.7-mile radius of the heliport excluding the airspace east of long. 123°55'51" W, and within 1.2 miles either side of the heliport's 291° bearing extending to the 6.3-mile radius.

* * * * *

Issued in Des Moines, Washington, on October 5, 2026.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2026–21978 Filed 10–27–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2026–8548; Airspace Docket No. 26–AGL–16]

RIN 2120–AA66

Establishment of Class E Airspace; Ottawa, IL; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on September 22, 2026, establishing Class E airspace at OSF St Elizabeth Medical Center Heliport, Ottawa, IL. This action corrects a typographical error in the airspace legal description.

DATES: The effective date of the final rule published in the **Federal Register** on September 22, 2026 remains 0901 UTC, December 24, 2026. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11M, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Airspace Regulation Group, Operational Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Raul Garza Jr., Federal Aviation Administration, Operations Support Group, Central Service Center, 10101

Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5874.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule for Docket No. FAA-2026-8548 in the **Federal Register** (91 FR 59987; September 22, 2026), establishing Class E airspace at OSF St Elizabeth Medical Center Heliport, Ottawa, IL. After publication of the final rule, an FAA database review noted that the incorrect heliport (OSF St Francis Medical Center Heliport) was used in the legal description. This action replaces the incorrect heliport with the correct heliport, OSF St Elizabeth Medical Center Heliport. This correction represents a ministerial change. It does not change the airspace dimensions or operating requirements. Accordingly, the FAA finds good cause that recirculating the NPRM for notice and comment is unnecessary.

Correction of Final Rule

Accordingly, pursuant to the authority delegated to me, the final rule for Docket No. FAA-2026-8548, as published in the **Federal Register** on September 22, 2026 (91 FR 59987; FR Doc. 2026-19391), is corrected as follows:

On page 59988, in the third column, amend Paragraph 6005 “Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.” by revising the legal description for “AGL IL E5 Ottawa, IL” to read as follows:

AGL IL E5 Ottawa, IL [Establish]

OSF St Elizabeth Medical Center Heliport, IL
(Lat. 41°21'30" N, long 88°49'30" W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the OSF St Elizabeth Medical Center Heliport.

* * * * *

Issued in Fort Worth, Texas, on October 26, 2026.

Jerry J. Creecy,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2026-21995 Filed 10-27-26; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2026-9835; Airspace
Docket No. 26-AGL-19]

RIN 2120-AA66

Establishment of Class E Airspace; DeKalb, IL; Correction

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on September 22, 2026, establishing Class E airspace at Northwestern Memorial Healthcare Heliport, DeKalb, IL. Specifically, this action corrects a typographic error in the airspace legal description.

DATES: The effective date of the final rule published in the **Federal Register** on September 22, 2026, remains 0901 UTC February 18, 2027. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments. **ADDRESSES:** FAA Order JO 7400.11M, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Airspace Regulation Group, Policy Directorate, Federal Aviation Administration, 800 Independence Avenue SW, Washington DC 20591; telephone: (202) 267-8783.

FOR FURTHER INFORMATION CONTACT: Raul Garza Jr., Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5874.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule for Docket No. FAA-2026-9835 in the **Federal Register** (91 FR 66635; September 22, 2026), establishing Class E airspace at Northwestern Memorial Healthcare Heliport, DeKalb, IL. After publication of the final rule, an FAA database review noted that the incorrect state (OH) was used in the legal description. This final rule correction replaces the incorrect state with the correct state, IL. This correction represents a ministerial change. It does not change the airspace dimensions or operating requirements. Accordingly, the FAA finds good cause that

recirculating the NPRM for notice and comment is unnecessary.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the final rule for Docket No. FAA-2026-9835, as published in the **Federal Register** on September 22, 2026 (91 FR 66635; FR Doc. 2026-21563), is corrected as follows:

On page 66636, in the second column, amend Paragraph 6005 “Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.” by revising the legal description for “AGL IL E5 DeKalb, IL” to read as follows:

AGL IL E5 DeKalb, IL [Establish]

Northwestern Memorial Healthcare Heliport,
IL

(Lat. 41°57'38" N, long. 88°43'18" W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Northwestern Memorial Healthcare Heliport.

* * * * *

Issued in Fort Worth, Texas, on October 26, 2026.

Jerry J. Creecy,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2026-21991 Filed 10-27-26; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 13

[Docket No. NPS-2026-0034]

RIN 1024-AE96

Alaska; Wildlife, Harvest, and Access; Correction

AGENCY: National Park Service, Interior.

ACTION: Final rule; correction.

SUMMARY: The National Park Service (NPS) is correcting a final rule that appeared in the **Federal Register** on October 19, 2026. The rule amended regulations for hunting, fishing, trapping, and other harvest-related activities in Alaska and the procedures used to restrict public use and access in Alaska park areas, including for subsistence.

DATES: Effective November 18, 2026.

FOR FURTHER INFORMATION CONTACT: Don Striker, Regional Director, Alaska Regional Office, 240 West 5th Ave., Anchorage, AK 99501; phone (907) 227-6163; email: AKR_Regulations@nps.gov. Individuals in the United States who are

deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In FR Doc, 2026–21299 appearing on page 65985 in the **Federal Register** of Monday, October 19, 2026, the following correction is made.

§ 13.420 [Corrected]

■ On page 65999, in the second column, in § 13.420, in amendment 8, the instruction “b. Revise the definitions for “Handicraft”; and “Subsistence uses”.” is corrected to read “b. Revise the definition for “Handicraft”; and the introductory text of the definition for “Subsistence uses”.”.

John Calhoun,

Chief, Division of Regulations, Jurisdiction, and Special Park Uses, National Park Service.

[FR Doc. 2026–21965 Filed 10–27–26; 8:45 am]

BILLING CODE 4312–52–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 770

[EPA–HQ–OPPT–2017–0245; FRL–12941–02–OCSPP]

RIN 2070–AL36

Voluntary Consensus Standards Update; Formaldehyde Emission Standards for Composite Wood Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is publishing a final rule to update the incorporation by reference of several voluntary consensus standards in the Agency’s formaldehyde standards for composite wood products regulations under the Toxic Substances Control Act (TSCA) due to the standards having been updated or superseded by the issuing organizations. These new standards primarily update test methods and product standards concerning composite wood products that use formaldehyde. EPA is also conforming these updated standards in the scope and definitional sections in the final rule and incorporating by reference a new small scale quality control chamber test method, similar to current methods

already incorporated by reference. EPA is also removing one standard that was previously incorporated by reference to avoid redundancy, given that another identical, internationally recognized version of the standard is already incorporated by reference in this rule.

DATES: This final rule is effective on November 27, 2026. The incorporation by reference of certain material listed in the rule is approved by the Director of the Federal Register as of November 27, 2026. The incorporation by reference of certain other material listed in the rule was approved by the Director of the Federal Register as of February 10, 2017, February 7, 2018, August 21, 2019, and March 23, 2023.

ADDRESSES: The docket for this action is identified by docket identification (ID) number EPA–HQ–OPPT–2017–0245, using the Federal eRulemaking Portal at <https://www.regulations.gov>. Additional instructions on visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Maxim Pohl, Existing Chemicals Risk Management Division (Mail Code 5133G), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2827; email address: pohl.maxim@epa.gov.

For general information contact: The TSCA Assistance Information Service Hotline, Goodwill Vision Enterprises, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (800) 471–7127 or (202) 554–1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this final rule if you manufacture (including import), sell, supply, or offer for sale in the United States any of the following: hardwood plywood, medium-density fiberboard, particleboard, and/or products containing these composite wood materials. You may also be affected by this final rule if you test or work with certification firms that certify such materials. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather it provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Veneer, plywood, and engineered wood product manufacturing (NAICS code 3212).
- Manufactured home (mobile home) manufacturing (NAICS code 321991).
- Prefabricated wood building manufacturing (NAICS code 321992).
- Furniture and related product manufacturing (NAICS code 337).
- Furniture merchant wholesalers (NAICS code 42321).
- Lumber, plywood, millwork, and wood panel merchant wholesalers (NAICS code 42331).
- Other construction material merchant wholesalers (NAICS code 423390) (e.g., merchant wholesale distributors of manufactured homes (i.e., mobile homes) and/or prefabricated buildings).
- Furniture stores (NAICS code 4421).
- Building material and supplies dealers (NAICS code 4441).
- Manufactured (mobile) home dealers (NAICS code 45393).
- Motor home manufacturing (NAICS code 336213).
- Travel trailer and camper manufacturing (NAICS code 336214).
- Recreational vehicle (RV) dealers (NAICS code 441210).
- Recreational vehicle merchant wholesalers (NAICS code 423110).
- Engineering services (NAICS code 541330).
- Testing laboratories (NAICS code 541380).
- Administrative management and general management consulting services (NAICS code 541611).
- All other professional, scientific, and technical services (NAICS code 541990).
- All other support services (NAICS code 561990).
- Business associations (NAICS code 813910).
- Professional organizations (NAICS code 813920).

If you have any questions regarding the applicability of this action, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency’s authority for taking this action?

EPA is publishing this final rule pursuant to the authority in section 601 of TSCA, 15 U.S.C. 2697, relating to formaldehyde emission standards for composite wood products.

C. What action is the Agency taking?

The Agency is issuing this final rule to take action on a recent Notice of Proposed Rulemaking (91 FR 6161) issued on February 11, 2026, including by addressing the comments received on the proposal.

The Agency is taking final action on the following:

1. Update Incorporation-By-Reference (IBR) for Certain Voluntary Consensus Standards

EPA is finalizing an update to the Incorporation-By-Reference (IBR) for certain voluntary consensus standards in 40 CFR 770.99 to reflect the most current standards issued by the relevant standards organizations. The relevant standards organizations updated these standards after EPA incorporated them in 40 CFR 770.99. The final rule will require regulated entities to adhere to the updated editions of the voluntary consensus standards when complying with the requirements of 40 CFR part 770. During the public comment period for the proposed rule, EPA received eight comments in support of updating these standards. These amendments are further explained in Unit II.B.

2. Addition of ISO 12460–2:2024(en) as an Alternative Quality Control Test Method

EPA is also finalizing the incorporation by reference of an additional small scale quality control chamber test method, ISO 12460–2:2024(en), in 40 CFR 770.99. This new standard will provide regulated entities with an additional quality control test method to choose from in 40 CFR 770.20(b). EPA received eight comments on the proposed rule in support of this standard's inclusion. This new standard is further explained in Unit II.B.

3. Removal of British Standards Institute Standard BS EN ISO 12460–3

The proposed rule published in February 2026 included an update for British Standards Institute (BSI) standard BS EN ISO 12460–3:2023, as well as a request for comment on whether this standard should be retained in the final rule, given that an identical, international version (ISO 12460–3:2023) was also proposed for incorporation into the rule. EPA received three comments on the proposed rule supporting the removal of BS EN ISO 12460–3 from the final rule. To avoid redundancy and potential confusion for stakeholders, EPA is no longer incorporating the updated standard BS EN ISO 12460–3:2023 and is removing the standard BS EN ISO 12460–3:2020 from 40 CFR 770.20(b)(1)(iii) and 40 CFR 770.99. This amendment is further explained in Unit II.B.

4. Conform Voluntary Consensus Standards in Scope and Definitions

As a result of the final list of updated standards in Unit II.B., EPA is finalizing an update to 40 CFR 770.1 and 770.3 to reflect the current standards that are incorporated by reference in 40 CFR 770.99. EPA received eight comments on the proposed rule in support of these updates to reflect current standards which are in use.

D. Why is the Agency taking this action?

The Agency is taking final action to update the incorporation by reference for several voluntary consensus standards at 40 CFR 770.99 to their current editions to address outdated, superseded, and withdrawn standards that have been updated between 2022 and 2024. These updates are needed because several of the standards in 40 CFR 770.99 are outdated. EPA is also taking final action to conform these voluntary consensus standards in the scope and definitional sections of 40 CFR part 770 to reflect the current editions that must be used by regulated entities. EPA believes that this action is warranted to facilitate regulated entities using the most up to date voluntary consensus standards to comply with the regulation at 40 CFR part 770. EPA is also taking final action to incorporate by reference at 40 CFR 770.99 an additional small scale quality control chamber test method, ISO 12460–2:2024(en), to provide stakeholders with an additional option for quality control testing. EPA is also no longer incorporating the updated BSI standard BS EN ISO 12460–3:2023 and is removing the BSI standard BS EN ISO 12460–3:2020 from the final rule because an identical, international version (ISO 12460–3:2023) is being updated with this final action. EPA believes this is warranted because having duplicative standards is redundant, offers no technical value to the program, and has the potential to create confusion for the regulated community.

E. What are the incremental economic impacts?

EPA anticipates no additional costs to stakeholders associated with this final rule for updated standards. This is a routine action that updates outdated voluntary consensus standards incorporated by reference at 40 CFR part 770, and includes a new, optional quality control test method. Removal of the standard BS EN ISO 12460–3:2020 is not anticipated to have any economic impact, given that the test method it describes is still available to stakeholders through ISO 12460–3:2023.

II. Background

A. Regulatory Overview

1. Formaldehyde Emission Standards for Composite Wood Products

The Formaldehyde Standards for Composite Wood Products Act of 2010 (Pub. L. 111–199, 124 Stat. 1359) created Title VI of TSCA (15 U.S.C. 2697), established emission standards for formaldehyde from composite wood products, and directed EPA to implement and enforce a number of provisions covering composite wood products. On December 12, 2016, EPA published a final rule (2016 final rule) (Ref. 1) to reduce exposure to formaldehyde emissions from certain wood products produced domestically or imported into the United States. EPA worked with the California Air Resource Board (CARB) to help align the 2016 final rule with the Airborne Toxics Control Measure (ATCM) (Ref. 2) to the extent EPA deemed appropriate and practical considering TSCA Title VI. By including provisions for laminated products, product-testing requirements, labeling, recordkeeping, and import certification, the 2016 final rule requires that hardwood plywood, medium-density fiberboard, and particleboard products sold, supplied, offered for sale, imported to, or manufactured in the United States be in compliance with the emission standards. The 2016 final rule also established a third-party certification program for laboratory testing and oversight of formaldehyde emissions from manufactured and/or imported composite wood products.

2. 2018 Voluntary Consensus Standards Amendment

On February 7, 2018, EPA published a final rule (Ref. 3) to update several voluntary consensus standards incorporated by reference at 40 CFR 770.99. These updates applied to emission testing methods and regulated composite wood product construction characteristics. Several of the organizations that develop voluntary consensus standards (*i.e.*, technical specifications for products or processes developed by standard-setting bodies) had updated, superseded, and/or withdrawn their standards through the normal course of business to take into account new information, technology, and methodologies.

3. 2019 Technical Issues Amendment

On August 21, 2019, EPA amended 40 CFR part 770 via a final rule (2019 final rule) (Ref. 4) to address certain technical issues. The 2019 final rule:

- Further aligned testing requirements with the CARB ATCM;
- Clarified provisions addressing non-complying lots and how those provisions apply to fabricators, importers, retailers, and distributors who are notified by panel producers that composite wood products they were supplied are found to be non-compliant after those composite wood products have been further fabricated into component parts or finished goods;
- Clarified that regulated composite wood products and finished goods containing composite wood products must be labeled at the point of manufacture or fabrication, and if imported, the label must be applied to the products as a condition of importation;
- Addressed TSCA Title VI “manufactured-by” date issues; and
- Updated two voluntary consensus standards that were incorporated by reference in 40 CFR 770.99.

4. 2023 Voluntary Consensus Standards Amendment

On February 21, 2023, EPA published a final rule (2023 final rule) (Ref. 5) that amended 40 CFR part 770 to, among other things:

- Update the incorporation by reference for ten voluntary consensus standards to reflect the current editions that are in use by regulated entities and industry stakeholders. These updates were needed to ensure continued consistency with the standards adopted and used by industry.
- Allow for remote inspections in the event of unsafe conditions that would prevent a third-party certifier (TPC) from traveling in-person to the area. During the COVID-19 public health emergency, EPA provided temporary flexibility to allow TPCs to conduct remote inspections to satisfy the requirements of the rule. EPA made this flexibility permanent and allowed TPCs to conduct the required initial on-site inspection or quarterly inspections and sample collections remotely when in-person, on-site inspections are temporarily infeasible because of unsafe conditions.
- Include certain technical corrections and updates to create additional flexibilities for the third-party certification process, as well as clarifying language as it relates to the production of wood products. Those corrections better aligned EPA’s rule with the CARB requirements.

B. Final Rule Amendments

1. Voluntary Consensus Standards IBR Update

a. IBR Update

EPA is taking final action to update the IBR of certain voluntary consensus standards in 40 CFR 770.99 to reflect the most recent editions of the following standards assembled by the American National Standards Institute (ANSI), the American Society for Testing and Materials (ASTM), the International Organization for Standardization (ISO), and the National Institute of Standards and Technology (NIST):

i. Product Standard for Structural Glued Laminated Timber (ANSI A190.1–2022)

This standard was initiated by the Engineered Wood Association (APA) and approved through ANSI. The ANSI standard details the specific requirements for production, inspection, testing and certification of structural glued laminated timber. The standard also describes a quality control system for the laminator, which covers plant qualification, daily quality control, product marking, and the functions of an accredited inspection agency. ANSI last updated this standard on February 17, 2022 (Ref. 6). EPA is taking final action to update the version of the standard incorporated by reference in 40 CFR 770.99 from ANSI A190.1–2017 to ANSI A190.1–2022.

ii. Standard Test Method for Determining Formaldehyde Levels From Wood Product Using a Desiccator (ASTM D5582–22)

This standard was issued by ASTM and identifies procedures for testing formaldehyde emission potential from wood products by measuring airborne formaldehyde after samples of a specified surface area are placed in a small distilled water reservoir within a closed desiccator for 2 hours. The ASTM standard was last updated in August 2022 (Ref. 7). EPA is taking final action to update the version of the standard incorporated by reference in 40 CFR 770.99 from ASTM D5582–14 to ASTM D5582–22.

iii. Standard Test Method for Determining Formaldehyde Concentrations in Air From Wood Products Using a Small-Scale Chamber (ASTM D6007–22)

This standard was issued by ASTM and describes the procedure for using a small-scale chamber test method to measure formaldehyde concentrations in air emitted by wood product test specimens under defined test conditions of temperature and relative humidity.

Results from the small-scale method are intended to be comparable to results obtained from testing larger samples using the large chamber test method, described in ASTM E1333. This ASTM standard was last updated in August 2022 (Ref. 8). EPA is taking final action to update the version of the standard incorporated by reference in 40 CFR 770.99 from ASTM D6007–14 to ASTM D6007–22.

iv. Standard Test Method for Determining Formaldehyde Concentrations in Air and Emission Rates From Wood Products Using a Large Chamber (ASTM E1333–22)

This standard was issued by ASTM and describes the procedure for using a large chamber test method to measure formaldehyde concentration in air and emission rate from wood products under conditions designed to simulate product use, while maintaining specific test conditions of temperature and relative humidity. The standard was last updated in August 2022 (Ref. 9). EPA is taking final action to update the version of the standard incorporated by reference in 40 CFR 770.99 from ASTM E1333–14 to ASTM E1333–22.

v. Wood-Based Panels—Determination of Formaldehyde Release—Part 3: Gas Analysis Method (ISO 12460–3:2023(E))

This standard was approved through ISO and describes a procedure for determination of accelerated formaldehyde release from wood-based panels. ISO 12460–3:2023(E) is identical to BS EN ISO 12460–3:2023, which is no longer included in this update and is being removed from 40 CFR 770.99. This version, ISO 12460–3:2023(E), was incorporated to avoid potential confusion by regulated stakeholders and allow manufacturers to use a single standard irrespective of their country. The standard was last updated in September 2023 (Ref. 10). EPA is taking final action to update the version of the standard incorporated by reference in 40 CFR 770.99 from ISO 12460–3:2020(E) to ISO 12460–3:2023(E).

vi. Voluntary Product Standard PS 1–22, Structural Plywood (PS 1–22)

This standard was issued by NIST and describes the principal types and grades of structural plywood, covering the wood species, veneer grading, adhesive bonds, panel construction and workmanship, dimensions and tolerances, marking, moisture content and packaging of structural plywood intended for construction and industrial uses. Test methods to determine compliance and a glossary of trade terms and definitions are included, as is

a quality certification program involving inspection, sampling, and testing of products identified as complying with this standard by qualified testing agencies. The NIST standard was last updated on October 2, 2023 (Ref. 11). EPA is taking final action to update the version of the standard incorporated by reference in 40 CFR 770.99 from PS 1–19 to PS 1–22.

b. Addition of ISO 12460–2:2024(en) as an Alternative Quality Control Test Method

EPA is taking final action to add ISO 12460–2:2024(en), Wood-based panels—Determination of Formaldehyde Release—Part 2: Small-scale Chamber Method (Ref. 12), as a quality control test method in 40 CFR 770.20(b)(1) and to IBR the standard in 40 CFR 770.99. This standard was approved through ISO and describes the procedure for using a small-scale chamber test method to test formaldehyde emissions from wood products under defined test conditions of temperature, relative humidity, loading and air exchange rate by measuring the concentrations of formaldehyde in air from samples of a specified surface area. This standard is a small scale quality control chamber test method that EPA is taking final action to incorporate by reference as an allowable alternative quality control test method, due to its similarity to other standards currently incorporated by reference for quality control methods, and to allow regulated entities to make use of the wider range of analytical methods the standard allows, such as laser absorption spectroscopy.

Industry has requested including the latest testing methodology which allows for greater industry flexibility in choosing quality control methods that best fit their circumstances. Including this additional standard also aligns with the CARB ATCM, which recently incorporated ISO 12460–2:2024(en) as a valid small scale quality control chamber test method. EPA believes that this action is warranted to facilitate regulated entities using the most up-to-date voluntary consensus standards to comply with the regulation at 40 CFR part 770 as well as align with current CARB requirements. Based on its similarity to other standards currently incorporated by reference for quality control methods, requests from industry to include the latest testing methodology, and support from public comments, EPA is taking final action to add this new ISO standard as a quality control method in 40 CFR 770.20(b)(1) and to incorporate it by reference in 40 CFR 770.99.

EPA will initiate additional notice-and-comment rulemaking when necessary to reflect any future changes to voluntary consensus standards incorporated by reference in 40 CFR 770.99.

c. Removal of British Standards Institute Standard BS EN ISO 12460–3

Because BS EN ISO 12460–3 and ISO 12460–3 are identical standards published by different standards development organizations, EPA is taking final action to consolidate 40 CFR 770.99 to only include the international version, ISO 12460–3:2023. This final rule removes the standard BS EN ISO 12460–3:2020 from the list of allowable quality control methods in 40 CFR 770.20(b)(1)(iii) and the list of standards approved for IBR in 40 CFR 770.99. The exact same procedure for determination of accelerated formaldehyde release from wood-based panels described by BS EN ISO 12460–3 is still available to stakeholders through ISO 12460–3:2023.

d. Availability

Copies of the standards identified in these sections II.B.1.a. and II.B.1.b. of **SUPPLEMENTARY INFORMATION** are available for inspection at the OPPT Docket in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA, West Bldg., 1301 Constitution Ave. NW, Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. If you have a disability and the format of any material on an EPA web page interferes with your ability to access the information, please contact EPA's Rehabilitation Act Section 508 (29 U.S.C. 794d) Program at <https://www.epa.gov/accessibility/forms/contact-us-about-section-508-accessibility> or via email at section508@epa.gov. To enable us to respond in a manner most helpful to you, please indicate the nature of the accessibility issue, the web address of the requested material, your preferred format in which you want to receive the material (electronic format (ASCII, etc.), standard print, large print, etc.), and your contact information. Additionally, each of these standards can be obtained directly from the publisher or standards development organization, as described in the following paragraphs.

i. ANSI A190.1 2022

Electronic copies of these materials may be obtained from APA at no cost at: <https://www.apawood.org/>. Copies of

this standard may also be obtained from APA—The Engineered Wood Association, 7011 South 19th Street, Tacoma, WA 98466, or by calling (253) 565–6600.

ii. ASTM D5582–22, ASTM D6007–22 and ASTM E1333–22

Copies of these materials may be obtained from ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959, or by calling (610) 832–9585, or at <http://www.astm.org>. ASTM standards referenced in this rule are also available for public review in read-only format in the ASTM Reading Room at <https://www.astm.org/standards-and-solutions/standards-and-publications/reading-room>.

iii. ISO 12460–3:2023(E) and ISO 12460–2:2024(en)

Copies of these materials may be obtained from the International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH–1211, Geneva 20, Switzerland, or by calling +41–22–749–01–11, or at <http://www.iso.org>. ISO standards referenced in this rule are also available for public review in read-only format on the ANSI Standards Incorporated by Reference Portal at <https://ibr.ansi.org/>.

iv. Voluntary Product Standard PS 1–22

Electronic copies of these materials may be obtained from the NIST at no cost at: <http://www.nist.gov>. You may purchase printed copies of these materials from NIST by calling (800) 553–6847. You must have an order number to purchase a NIST publication. Order numbers may be obtained from the Public Inquiries Unit at (301) 975–NIST. Mailing address: Public Inquiries Unit, NIST, 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899–1070. In addition, you may also purchase printed copies of NIST publications from the U.S. Government Printing Office (GPO) if you have a GPO stock number. GPO orders may be mailed to: U.S. Government Printing Office, P.O. Box 979050, St. Louis, MO 63197–9000, placed by telephone at (866) 512–1800 (DC Area only: (202) 512–1800), or faxed to (202) 512–2104.

2. Technical Correction(s)

To conform to the list of updated standards and the addition of one new standard listed in in sections II.B.1.a. and II.B.1.b. of **SUPPLEMENTARY INFORMATION**, EPA is taking final action to update 40 CFR 770.1 and 770.3 to reflect the standards that EPA is incorporating by reference in 40 CFR 770.99.

C. Rationale for Rule Changes

EPA is taking final action to update the incorporation by reference of certain voluntary consensus standards in 40 CFR 770.99 that have been updated, superseded, or withdrawn by the issuing organizations. These new standards are needed to reflect the most recent editions of those standards issued by the relevant standards organizations. EPA is also taking final action with the addition of a new standard, ISO 12460-2:2024(en), to allow industry greater flexibility in choosing quality control methods that best fit their circumstances, such as laser absorption spectroscopy. This additional standard also aligns with the CARB ATCM, which recently incorporated ISO 12460-2:2024(en) as a valid small scale quality control chamber test method. EPA believes that this action is warranted to facilitate regulated entities using the most up-to-date voluntary consensus standards to comply with the regulation at 40 CFR part 770 as well as align with current CARB requirements. EPA is also taking final action to remove the BSI standard BS EN ISO 12460-3:2020 as a standard approved for IBR in 40 CFR 770.99, and is no longer incorporating the updated version BS EN ISO 12460-3:2023 to avoid redundancy and potential confusion for stakeholders, given an identical, international version of the standard (ISO 12460-3:2023) is also incorporated by reference in this rule.

III. Summary of Public Comments

EPA received nine public comments in total during the 30-day public comment period for the proposed rule (91 FR 6161) and carefully considered each submission. One commenter (EPA-HQ-OPPT-2017-0245-0058) did not raise a substantive issue relevant to the proposed rule.

The remaining eight comments were directly relevant to the proposed rule. All eight relevant commenters supported the proposed updates to the standards and the inclusion of the new quality control method, ISO 12460-2:2024(en).

Three commenters (EPA-HQ-OPPT-2017-0245-0056; EPA-HQ-OPPT-2017-0245-0061; EPA-HQ-OPPT-2017-0245-0064) supported EPA removing the British Standards Institute standard BS EN ISO 12460-3 from the final rule and confirmed that retaining this standard would be redundant, given that an identical, international version (ISO 12460-3:2023) is also incorporated into the rule. EPA has revised the rule to remove BS EN ISO 12460-3:2020

from 40 CFR 770.20(b)(1)(iii) and 40 CFR 770.99.

Three commenters (EPA-HQ-OPPT-2017-0245-0056; EPA-HQ-OPPT-2017-0245-0059; EPA-HQ-OPPT-2017-0245-0064) requested that EPA define “significant change” as it is used in the TSCA Title VI rule, specifically in terms of what constitutes a significant change that would render an established equivalence or correlation between different test methods invalid, thus requiring a redemonstration of equivalence. This terminology is not new; the phrase “significant change” has appeared in 40 CFR 770.20(d) since the 2016 TSCA Title VI final rule and is not introduced by the updates in this action. Generally, a significant change may be any change in equipment, procedure, or the qualifications of testing personnel that a technically competent person would expect to alter the established statistical relationship between test methods. See, for example, the discussion of the topic in EPA’s Frequent Questions for Regulated Stakeholders about Implementing the Formaldehyde Standards for Composite Wood Products Act at Question 2 and Question 5 under the section on “Starting-Up New Mills,” available online at <https://www.epa.gov/formaldehyde/frequent-questions-regulated-stakeholders-about-implementing-formaldehyde-standards#newmills>. EPA will consider publishing additional examples of what may constitute a significant change at a future date.

Two commenters (EPA-HQ-OPPT-2017-0245-0056; EPA-HQ-OPPT-2017-0245-0059) requested that EPA address the timing expectation for transitioning to the new standards being updated or adopted with this rulemaking. Beyond the effective date of this final rule’s amendments being 30 days after publication of this final rule, EPA is not establishing an additional transition period in this action because the updated editions incorporated by reference are technically consistent with the previously referenced editions and are not expected to affect compliance determinations or implementation. The new standard being incorporated, ISO 12460-2:2024(en), introduces an optional method for quality control testing, and thus imposes no transitional burden on regulated entities. In future actions where EPA proposes to incorporate editions that introduce substantive changes that could affect implementation (e.g., procedures, calculations, or apparatus), the Agency intends to evaluate and, as appropriate, propose defined transition provisions to minimize disruption.

One commenter (EPA-HQ-OPPT-2017-0245-0056) requested that EPA clarify how the new standard ISO 12460-2:2024(en) fits within Quality Control Limit (QCL) and correlation requirements. ISO 12460-2:2024(en) can be used in the same manner that other quality control methods are used to conduct routine quality control testing, at a frequency specified in 40 CFR 770.20(b)(2), with results reported as specified in 40 CFR 770.20(b)(3). ISO 12460-2:2024(en) is subject to the same correlation demonstration requirements as all other quality control methods, as described in 40 CFR 770.20(d)(2). The same commenter requested that EPA clarify timing expectations for equivalence demonstrations, and that such demonstrations are a standing laboratory requirement supporting the use of ASTM D6007 for quarterly testing rather than a condition that could delay routine compliance activities. As specified in 40 CFR 770.20(c)(1), quarterly testing must be performed using ASTM E1333, or, with a showing of equivalence pursuant to 40 CFR 770.20(d), ASTM D6007. When utilizing ASTM D6007 for either quarterly testing or quality control testing (or another method listed in 40 CFR 770.20(b)(1) for quality control testing), equivalence or correlation demonstrations must be conducted at a frequency specified in 40 CFR 770.20(d). As also specified in 40 CFR 770.20(d), if the TPC laboratory’s ASTM E1333 or equivalent ASTM D6007 test chamber is used for panel producer quality control testing, no correlation as determined in 40 CFR 770.20(d)(2) would be required.

Finally, the same commenter asked that EPA clarify documentation expectations for cluster and threshold approaches for demonstrating equivalence for quality control methods listed in 40 CFR 770.20(b). As specified in 40 CFR 770.40(a)(2), records should be maintained of all ongoing quality control testing, and must include the date, the product type tested, the lot number that the tested material represents, the test method used, and the test results. As described in 40 CFR 770.20(b)(1), equivalence or correlation testing is a part of quality control testing. Records should demonstrate compliance with all required aspects of methods described in 40 CFR 770.20(d)(2), if utilized.

EPA thanks all the submitters for their comments related to this final rule. When necessary, EPA intends to reflect any future changes to voluntary consensus standards incorporated by reference in 40 CFR 770.99 through additional notice-and-comment rulemaking.

IV. References

The following is a list of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Formaldehyde Emission Standards for Composite Wood Products. Final Rule. **Federal Register**. 81 FR 89674, December 12, 2016 (FRL–9949–90).
2. California Environmental Protection Agency Air Resources Board. Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products. Final Regulation Order. April 2008.
3. EPA. Voluntary Consensus Standards Update; Formaldehyde Emission Standards for Composite Wood Products. Final Rule. **Federal Register**. 83 FR 5340, February 7, 2018 (FRL–9972–68).
4. EPA. Technical Issues; Formaldehyde Emission Standards for Composite Wood Products. Final Rule. **Federal Register**. 84 FR 43517, August 21, 2019 (FRL–9994–47).
5. EPA. Voluntary Consensus Standards Update; Formaldehyde Emission Standards for Composite Wood Products. Final Rule. **Federal Register**. 88 FR 10468, February 21, 2023 (FRL–8452–01–OCSP).
6. American National Standards Institute (ANSI). ANSI A190.1–2022, Product Standard for Structural Glued Laminated Timber.
7. American Society for Testing and Materials (ASTM). ASTM D5582–22, Standard Test Method for Determining Formaldehyde Levels from Wood Products Using a Desiccator.
8. ASTM. ASTM D6007–22, Standard Test Method for Determining Formaldehyde Concentrations in Air from Wood Products Using a Small-Scale Chamber.
9. ASTM. ASTM E1333–22, Standard Test Method for Determining Formaldehyde Concentrations in Air and Emission Rates from Wood Products Using a Large Chamber.
10. International Organization for Standardization (ISO). ISO 12460–3:2023(E), Wood-based Panels—Determination of Formaldehyde Release—Part 3: Gas Analysis Method.
11. National Institute of Standards and Technology (NIST). PS 1–22, Structural Plywood.
12. ISO. ISO 12460–2:2024(en), Wood-based panels—Determination of formaldehyde release Part 2: Small-scale chamber method.

V. Statutory and Executive Order Reviews

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

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to Executive Order 12866 review have been documented in the docket.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is considered an Executive Order 14192 (90 FR 9065, January 31, 2025) deregulatory action. This final rule provides burden reduction by updating the incorporation by reference of several voluntary consensus standards in TSCA Title VI due to certain standards having been updated or superseded by the issuing organizations, aligning requirements with current industry practices. To avoid redundancy and potential confusion for stakeholders, EPA is no longer incorporating the updated standard BS EN ISO 12460–3:2023 and is removing the standard BS EN ISO 12460–3:2020 from 40 CFR 770.20(b)(1)(iii) and 40 CFR 770.99. This amendment is further explained in Unit II.B. EPA is also taking final action with the addition of a new standard, ISO 12460–2:2024, to allow industry greater flexibility in choosing quality controls methods that best fit their circumstances, such as laser absorption spectroscopy. This deregulatory action removes redundancy, aligns requirements with current industry practices and eliminates duplicative or outdated standards.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). This action does not create any new reporting or recordkeeping obligations. OMB previously approved the information collection activities contained in the existing regulations and assigned OMB control number 2070–0185.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a

substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, EPA concludes that the impact of concern for this action is any significant adverse economic impact on small entities, and the Agency is certifying that this action will not have a significant economic impact on a substantial number of small entities because it will impose no net burden on the small entities to the rule. The final rule updates the incorporation by reference of voluntary consensus standards in 40 CFR part 770 by adopting the most current versions of those standards, adding one new voluntary consensus standard as a quality control test method, and by removing one duplicative, redundant standard. The updated versions of the standards are substantially similar to the previous versions. EPA expects that many small entities are already complying with the updated versions of the standards listed Unit II.B. This action allows these entities the flexibility to use the most up to date versions of the standards instead of using outdated versions that do not reflect industry best practice. This action also adds one new voluntary consensus standard as a quality control test method in 40 CFR 770.20(b)(1), which regulated entities may opt to use in lieu of the other approved quality control methods, thereby increasing regulatory flexibility. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million (in 1995 dollars and adjusted annually for inflation) or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments. As discussed in Unit V.D., the final rule will impose no net regulatory burdens on the private sector.

F. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, E.O. 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern environmental health or safety risks that the Agency has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of Executive Order 13045. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health, EPA’s Policy on Children’s Health also does not apply.

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

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. As explained in Unit II.B, this action updates the IBR of certain voluntary consensus standards in 40 CFR 770.99 to reflect the most recent editions of the standards assembled by relevant international standards bodies, incorporates an additional standard by reference to allow the use of an alternative quality control test method, removes one standard from the list of allowable quality control methods because it is identical to another allowable quality control method that is already incorporated by reference. As explained in Unit II.C, this action also implements conforming technical corrections.

J. National Technology Transfer and Advancement Act (NTTAA)

This action involves technical standards subject to consideration under NTTAA section 12(d), 15 U.S.C. 272.

EPA has decided to use ANSI A190.1–2022, ASTM D5582–22, ASTM D6007–22, ASTM E1333–22, ISO 12460–3:2023(E), ISO 12460–2:2024(en) and PS 1–22. Additional information about these standards, including how to access them, is provided in Unit II.B.1. of **SUPPLEMENTARY INFORMATION**.

In addition, the following standards appear in the amendatory text of this document and have already been approved for the locations in which they appear, and the approval continues unchanged: ANSI A135.4–2012, ANSI A135.5–2012, ANSI A135.6–2012, ANSI A135.7–2012, ANSI/HPVA HP–1–2020, BS EN ISO 12460–5:2015, ISO/IEC 17011:2017(E), ISO/IEC 17020:2012(E), ISO/IEC 17025:2017(E), ISO/IEC 17065:2012(E), and PS 2–18.

K. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 770

Environmental protection, Formaldehyde, Incorporation by reference, Reporting and recordkeeping requirements, Third-party certification, Toxic substances, Wood.

Dated: October 22, 2026.

Douglas M. Troutman,
Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons set forth in the preamble, EPA amends 40 CFR part 770 as follows:

PART 770—FORMALDEHYDE STANDARDS FOR COMPOSITE WOOD PRODUCTS

■ 1. The authority citation for part 770 continues to read as follows:

Authority: 15 U.S.C. 2697(d).

■ 2. Amend § 770.1 by revising and republishing paragraphs (c)(3) and (7) to read as follows:

§ 770.1 Scope and applicability.

* * * * *

(c) * * *

(3) Structural plywood, as specified in PS 1–22 (incorporated by reference, see § 770.99).

* * * * *

(7) Glued laminated lumber, as specified in ANSI A190.1–2022, Standard for Wood Products—Structural Glued Laminated Timber (incorporated by reference, see § 770.99).

* * * * *

■ 3. Amend § 770.3 by revising and republishing the definitions for “Hardboard”, “Hardwood plywood”, and “Quality control limit or QCL” to read as follows:

§ 770.3 Definitions.

* * * * *

Hardboard means a composite panel composed of cellulosic fibers, consolidated under heat and pressure in a hot press by: A wet process; or a dry process that uses a phenolic resin, or a resin system in which there is no formaldehyde as part of the resin cross-linking structure; or a wet formed/dry pressed process; and that is commonly or commercially known, or sold, as hardboard, including any product conforming to one of the following ANSI standards: Basic Hardboard (ANSI A135.4–2012) (incorporated by reference, see § 770.99), Prefinished Hardboard Paneling (ANSI A135.5–2012) (incorporated by reference, see § 770.99), Engineered Wood Siding (ANSI A135.6–2012) (incorporated by reference, see § 770.99), or Engineered Wood Trim (ANSI A135.7–2012) (incorporated by reference, see § 770.99). There is a rebuttable presumption that products emitting more than 0.06 ppm formaldehyde as measured by ASTM E1333–22 (incorporated by reference, see § 770.99) or ASTM D6007–22 (incorporated by reference, see § 770.99) are not hardboard.

Hardwood plywood means a hardwood or decorative panel that is intended for interior use and composed of (as determined under ANSI/HPVA HP–1–2020 (incorporated by reference, see § 770.99)) an assembly of layers or plies of veneer, joined by an adhesive with a lumber core, a particleboard core, a medium-density fiberboard core, a hardboard core, a veneer core, or any other special core or special back material. Hardwood plywood does not include military-specified plywood, curved plywood, or any plywood specified in PS 1–22 (incorporated by reference, see § 770.99), or PS 2–18 (incorporated by reference, see § 770.99). In addition, hardwood plywood includes laminated products except as provided at § 770.4.

* * * * *

Quality control limit or QCL means the value from the quality control method test that is the correlative equivalent to the applicable emission standard based on the ASTM E1333–22 method (incorporated by reference, see § 770.99) or, upon showing equivalence in accordance with § 770.20(d), the

ASTM D6007–22 method (incorporated by reference, see § 770.99).

* * * * *

■ 4. Amend § 770.7 by revising and republishing paragraphs (a)(5)(i)(D) and (F), (b)(5)(i) introductory text, (c)(1)(ii) and (v), (c)(2)(iv) and (viii), (c)(4)(i)(B), and (c)(4)(v)(C) to read as follows:

§ 770.7 Third-party certification.

(a) * * *

(5) * * *

(i) * * *

(D) A review of the approach that the TPC laboratory will use for establishing correlation or equivalence between ASTM E1333–22 and ASTM D6007–22, if used, (incorporated by reference, see § 770.99) or allowable formaldehyde test methods listed under § 770.20.

* * * * *

(F) A review of the accreditation credentials of the TPC laboratory, including a verification that the laboratory has been accredited to ISO/IEC 17025:2017(E) (incorporated by reference, see § 770.99) with a scope of accreditation to include this part—Formaldehyde Standards for Composite Wood Products and the formaldehyde test methods ASTM E1333–22 and ASTM D6007–22, if used, by an EPA TSCA Title VI Laboratory AB (incorporated by reference, see § 770.99).

* * * * *

(b) * * *

(5) * * *

(i) *Accreditation.* EPA TSCA Title VI Laboratory ABs must determine the accreditation eligibility, and accredit if appropriate, each TPC seeking recognition under the EPA TSCA Title VI Third-Party Certification Program by performing an assessment of each TPC. The assessment must include an on-site assessment by the EPA TSCA Title VI Laboratory AB to determine whether the laboratory meets the requirements of ISO/IEC 17025:2017(E) (incorporated by reference, see § 770.99), is in conformance with ISO/IEC 17020:2012(E) (incorporated by reference, see § 770.99) and the EPA TSCA Title VI TPC requirements under this part including the formaldehyde test methods ASTM E1333–22 and ASTM D6007–22 (incorporated by reference, see § 770.99), if used. In performing the on-site assessment, the EPA TSCA Title VI Laboratory AB must:

* * * * *

(c) * * *

(1) * * *

(ii) Be, or have a contract with a laboratory that is, accredited by an EPA TSCA Title VI Laboratory AB to ISO/IEC 17025:2017(E) (incorporated by

reference, see § 770.99) with a scope of accreditation to include this part—Formaldehyde Standards for Composite Wood Products—and the formaldehyde test methods ASTM E1333–22 and ASTM D6007–22, if used (incorporated by reference, see § 770.99);

* * * * *

(v) Have demonstrated experience in performing or verifying formaldehyde emissions testing on composite wood products, including experience with test method ASTM E1333–22 and ASTM D6007–22, if used, (incorporated by reference, see § 770.99), and experience evaluating correlation between test methods. Applicant TPCs that have demonstrated experience with test method ASTM D6007–22 only, must be contracting testing with a laboratory that has a large chamber and demonstrate its experience with ASTM E1333–22.

* * * * *

(2) * * *

(iv) A copy of the TPC laboratory's certificate of accreditation from an EPA TSCA Title VI Laboratory AB to ISO/IEC 17025:2017(E) (incorporated by reference, see § 770.99) with a scope of accreditation to include this part—Formaldehyde Standards for Composite Wood Products—and the formaldehyde test methods ASTM E1333–22 and ASTM D6007–22 (incorporated by reference, see § 770.99), if used;

* * * * *

(viii) A description of the TPC's experience with test method ASTM E1333–22 and/or ASTM D6007–22, if used, (incorporated by reference, see § 770.99), and experience evaluating correlation between test methods. Applicant TPCs that have experience with test method ASTM D6007–22 only, must be contracting testing with a laboratory that has a large chamber and describe its experience with ASTM E1333–22; and

* * * * *

(4) * * *

(i) * * *

(B) Verify each panel producer's quality control test results compared with test results from ASTM E1333–22 and ASTM D6007–22, if used, (incorporated by reference, see § 770.99) by having the TPC laboratory conduct quarterly tests and evaluate test method equivalence and correlation as required under § 770.20;

* * * * *

(v) * * *

(C) Notification of a panel producer exceeding its established QCL for three consecutive quality control tests within 72 hours of the time that the TPC becomes aware of the third consecutive exceedance. The notice must include

the product type, dates of the quality control tests that exceeded the QCL, quality control test results, ASTM E1333–22 (incorporated by reference, see § 770.99) or ASTM D6007–22 method (incorporated by reference, see § 770.99) correlative equivalent values in accordance with § 770.20(d), the established QCL value(s) and the quality control method used.

* * * * *

■ 5. Amend § 770.10 by revising and republishing paragraph (b) introductory text to read as follows:

§ 770.10 Formaldehyde emission standards.

* * * * *

(b) The emission standards are based on test method ASTM E1333–22 (incorporated by reference, see § 770.99), and are as follows:

* * * * *

■ 6. Amend § 770.15 by revising and republishing paragraphs (c)(1)(v) and (c)(2)(iii) to read as follows:

§ 770.15 Composite wood product certification.

* * * * *

(c) * * *

(1) * * *

(v) At least five tests conducted under the supervision of an EPA TSCA Title VI TPC pursuant to test method ASTM E1333–22 or ASTM D6007–22 (incorporated by reference, see § 770.99). Test results obtained by ASTM D6007–22 must include a showing of equivalence in accordance with § 770.20(d)(1);

* * * * *

(2) * * *

(iii) At least five tests conducted under the supervision of an EPA TSCA Title VI TPC pursuant to test method ASTM E1333–22 or ASTM D6007–22 (incorporated by reference, see § 770.99). Test results obtained by ASTM D6007–22 must include a showing of equivalence in accordance with § 770.20(d)(1);

* * * * *

■ 7. Amend § 770.17 by revising and republishing paragraph (a)(3) to read as follows:

§ 770.17 No-added formaldehyde-based resins.

* * * * *

(a) * * *

(3) At least one test conducted under the supervision of an EPA TSCA Title VI TPC pursuant to test method ASTM E1333–22 or ASTM D6007–22 (incorporated by reference, see § 770.99). Test results obtained by ASTM D6007–22 must include a

showing of equivalence in accordance with § 770.20(d)(1); and

* * *

■ 8. Amend § 770.18 by revising and republishing paragraph (a)(3) to read as follows:

§ 770.18 Ultra low-emitting formaldehyde resins.

* * *

(a) * * *

(3) At least two tests conducted under the supervision of an EPA TSCA Title VI TPC pursuant to test method ASTM E1333–22 or ASTM D6007–22 (incorporated by reference, see § 770.99). Test results obtained by ASTM D6007–22 must include a showing of equivalence in accordance with § 770.20(d)(1); and

* * *

■ 9. Amend § 770.20 by:

■ a. Revising and republishing paragraphs (b)(1)(i) through (iii);

■ b. Adding paragraph (b)(1)(viii); and

■ c. Revising and republishing paragraphs (c)(1), (c)(2)(iv), (d) introductory text, (d)(1) introductory text, (d)(1)(i) through (iii), (d)(2) introductory text, and (d)(2)(i).

The revisions and addition read as follows:

§ 770.20 Testing requirements.

* * *

(b) * * *

(1) * * *

(i) ASTM D6007–22 (incorporated by reference, see § 770.99).

(ii) ASTM D5582–22 (incorporated by reference, see § 770.99).

(iii) ISO 12460–3:2023(E) (incorporated by reference, see § 770.99).

* * *

(viii) ISO 12460–2:2024(en) (incorporated by reference, see § 770.99).

* * *

(c) * * *

(1) *Allowable methods.* Quarterly testing must be performed using ASTM E1333–22 (incorporated by reference, see § 770.99) or, with a showing of equivalence pursuant to paragraph (d) of this section, ASTM D6007–22 (incorporated by reference, see § 770.99).

* * *

(2) * * *

(iv) Test results may represent a single chamber value or, if using the ASTM

D6007–22 apparatus, the average value of testing nine specimens representing evenly distributed portions of an entire panel. The nine specimens must be tested in groups of three specimens, resulting in three data points, which must be averaged to represent one test value for the panel those specimens represent.

* * *

(d) *Equivalence or correlation.*

Equivalence between ASTM E1333–22 (incorporated by reference, see § 770.99) and ASTM D6007–22 (incorporated by reference, see § 770.99) must be demonstrated by EPA TSCA Title VI TPCs at least once each year or whenever there is a significant change in equipment, procedure, or the qualifications of testing personnel, or reason to believe that the equivalence is no longer valid. Equivalence may be demonstrated between several similar model or size and construction ASTM E1333–22 (incorporated by reference, see § 770.99) and ASTM D6007–22 (incorporated by reference, see § 770.99) apparatuses located in the same EPA TSCA Title VI TPC laboratory. Once equivalence has been established for three consecutive years, equivalence must be demonstrated every two years or whenever there is a significant change in equipment, procedure, or the qualifications of testing personnel.

Correlation between ASTM E1333–22 (incorporated by reference, see § 770.99) or, upon a showing of equivalence in accordance with paragraph (d) of this section, ASTM D6007–22 (incorporated by reference, see § 770.99) and any other test method used for quality control testing must be demonstrated by EPA TSCA Title VI TPCs or panel producers, respectively, before the certification of composite wood products, and then whenever there is a significant change in equipment, procedure, the qualifications of testing personnel, or reason to believe that the correlation is no longer valid. Correlation may be established between several similar model or size and construction mill quality control test methods defined in paragraph (b)(1) of this section located at any one physical mill quality control testing laboratory to the EPA TSCA Title VI TPC laboratory's ASTM E1333–22 (incorporated by reference, see § 770.99) and/or ASTM D6007–22 (incorporated by reference, see § 770.99) apparatus. If the TPC laboratory's ASTM E1333–22 or equivalent ASTM D6007–22 test chamber is used for panel producer

quality control testing, no correlation as determined in paragraph (d)(2) of this section would be required. Equivalence and correlation sample selection should be conducted in accordance with paragraph (c)(2)(iv) of this section.

(1) *Equivalence between ASTM E1333–22 and ASTM D6007–22 when used by the TPC for quarterly testing.* Equivalence must be demonstrated for at least five comparison sample sets in each range tested by the TPC, which compare the results of the two methods. Equivalence must be demonstrated for any ranges listed in paragraph (d)(1)(iv) of this section that represent the formaldehyde emissions of composite wood products tested by the TPC.

(i) *Samples.* (A) For the ASTM E1333–22 method (incorporated by reference, see § 770.99), each comparison sample must consist of the result of testing panels, using the applicable loading ratios specified in the ASTM E1333–22 method (incorporated by reference, see § 770.99), from similar panels of the same product type tested by the ASTM D6007–22 method (incorporated by reference, see § 770.99).

(B) For the ASTM D6007–22 method (incorporated by reference, see § 770.99), each comparison sample shall consist of testing specimens representing portions of panels similar to the panels tested in the ASTM E1333–22 method (incorporated by reference, see § 770.99) and matched to their respective ASTM E1333–22 method (incorporated by reference, see § 770.99) comparison sample result. The ratio of air flow to sample surface area specified in ASTM D6007–22 (incorporated by reference, see § 770.99) must be used.

(C) The five comparison sample must consist of testing a minimum of five sample sets as measured by the ASTM E1333–22 method (incorporated by reference, see § 770.99).

(ii) *Average and standard deviation.* The arithmetic mean, $\bar{X}$, and standard deviation, S , of the difference of all comparison sets must be calculated using Equations 1 and 2 to this paragraph (d)(1)(ii), where $\bar{X}$ = arithmetic mean; S = standard deviation; n = number of sets; D_i = difference between the ASTM E1333–22 and ASTM D6007–22 method (incorporated by reference, see § 770.99) values for the i th set; and i ranges from 1 to n .

Equation 1 to paragraph (d)(1)(ii) – Arithmetic mean

$$\bar{X} = \sum_{i=1}^n D_i / n$$

Equation 2 to paragraph (d)(1)(ii) – Standard deviation

$$S = \sqrt{\sum_{i=1}^n (D_i - \bar{X})^2 / (n - 1)}$$

(iii) *Equivalence determination.* The ASTM D6007–22 method (incorporated by reference, see § 770.99) is considered equivalent to the ASTM E1333–22 method (incorporated by reference, see § 770.99) if the following condition is met: $|\bar{X}| + 0.88S \leq C$

Where C is equal to:

0.026 for the lower range;
0.038 for the intermediate range; and
0.052 for the upper range.

* * * * *

(2) *Correlation between ASTM E–1333–22 (incorporated by reference, see § 770.99), or equivalent ASTM D6007–22 (incorporated by reference, see § 770.99), and any quality control test method.* Correlation must be demonstrated by establishing an acceptable correlation coefficient (“ r ” value) or following the threshold approach at paragraph (d)(2)(i)(B) of this section.

(i) *Correlation.* The correlation must be based on a minimum sample size of five data pairs and a simple linear regression (unless the threshold approach at paragraph (d)(2)(i)(B) of this section is used) where the dependent variable (Y-axis) is the quality control test value and the independent variable (X-axis) is the ASTM E1333–22 (incorporated by reference, see § 770.99) test value or, upon a showing of equivalence in accordance with paragraph (d) of this section, the equivalent ASTM D6007–22 (incorporated by reference, see § 770.99) test value. Either composite wood products or formaldehyde emissions reference materials can be used to establish the correlation.

(A) *Cluster Approach.* A panel producer may work with its EPA TSCA Title VI TPC to develop a correlation and linear regression between the TPC’s ASTM E1333–22 (incorporated by reference, see § 770.99) or equivalent

ASTM D6007–22 (incorporated by reference, see § 770.99) test method and the panel producer’s quality control method under paragraph (b) of this section. In the event of clustered test results, a panel producer may fit a line through a point near the origin (the intersection of the X and Y axes) and the average value of the clustered data pairs. The point near the origin should represent the value for the EPA TSCA Title VI TPC’s ASTM E1333–22 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–22 (incorporated by reference, see § 770.99) test method and the panel producer’s quality control method under § 770.20(b) when each testing apparatus is empty or when a very low emitting sample is tested. The average value of the clustered data pairs represents the average of a minimum of five data pairs that compare the test results of the EPA TSCA Title VI TPC’s ASTM E1333–22 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–22 (incorporated by reference, see § 770.99) test method with the panel producer’s quality control method under paragraph (b) of this section. The line between the point near the origin and the average value of the cluster provides the linear regression. This line may be used by the panel producer and TPC to develop a quality control limit for the product.

(B) *Threshold Approach.* As an alternative to the linear regression and cluster approaches, a panel producer may use the average value of the clustered data pairs from the EPA TSCA Title VI TPC’s ASTM E1333–22 (incorporated by reference, see § 770.99) or equivalent ASTM D6007–22 (incorporated by reference, see § 770.99) test method and the panel producer’s quality control method under paragraph (b) of this section as the quality control limit for the product. In this approach,

no linear regression line is established. The average value would be assigned as the upper quality control limit for production of the subject composite wood product and must be below the applicable emission standard.

* * * * *

■ 11. Amend § 770.99 by revising and republishing paragraphs (a)(1), (b)(3) through (5), (c), (g), and (i)(1) to read as follows:

§ 770.99 Incorporation by reference.

* * * * *

(a) * * *
(1) ANSI A190.1–2022, Product Standard for Structural Glued Laminated Timber, Approved February 17, 2022; IBR approved for § 770.1(c).

* * * * *

(b) * * *
(3) ASTM D5582–22, Standard Test Method for Determining Formaldehyde Levels from Wood Products Using a Desiccator, Approved August 1, 2022; IBR approved for § 770.20(b).

(4) ASTM D6007–22, Standard Test Method for Determining Formaldehyde Concentrations in Air from Wood Products Using a Small-Scale Chamber, Approved August 1, 2022; IBR approved for §§ 770.3; 770.7(a) through (c); 770.15(c); 770.17(a); 770.18(a); 770.20(b) through (d).

(5) ASTM E1333–22, Standard Test Method for Determining Formaldehyde Concentrations in Air and Emission Rates from Wood Products Using a Large Chamber, Approved August 1, 2022; IBR approved for §§ 770.3; 770.7(a) through (c); 770.10(b); 770.15(c); 770.17(a); 770.18(a); 770.20(c) and (d).

(c) *BSI.* British Standards Institute, 12950 Worldgate Dr., Suite 800, Herndon, VA 20170; (800) 862–4977; www.bsigroup.com.

(1) BS EN ISO 12460–5:2015 E, Wood based panels.—Determination of

formaldehyde release—Part 5: Extraction method (called the perforator method), December 2015; IBR approved for § 770.20(b).

(2) [Reserved]

* * * * *

(g) ISO. International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH-1211, Geneve 20, Switzerland; +41-22-749-01-11; www.iso.org.

(1) ISO 12460-2:2024(en) Wood-based panels—Determination of formaldehyde release—Part 2: Small-scale chamber method, Second edition, February 2024; IBR approved for § 770.20(b).

(2) ISO 12460-3:2023(E), Wood-based panels—Determination of formaldehyde release—Part 3: Gas analysis method, Fourth edition, September 2023; IBR approved for § 770.20(b).

(3) ISO/IEC 17011:2017(E) Conformity assessments—Requirements for accreditation bodies accrediting conformity assessments bodies (Second Edition), November 2017; IBR approved for §§ 770.3; 770.7(a) and (b).

(4) ISO/IEC 17020:2012(E), Conformity assessment—Requirements for the operation of various bodies performing inspection, Second edition, 2012-03-01; IBR approved for §§ 770.3; 770.7(a) through (c).

(5) ISO/IEC 17025:2017(E), General requirements for the competence of testing and calibration laboratories (Third Edition), November 2017; IBR approved for §§ 770.3; 770.7(a) through (c).

(6) ISO/IEC 17065:2012(E), Conformity assessment—Requirements for bodies certifying products, processes and services, First edition, 2012-09-15; IBR approved for §§ 770.3; 770.7(a) and (c).

* * * * *

(i) * * *

(1) Voluntary Product Standard PS 1-22, Structural Plywood, effective October 2, 2023; IBR approved for §§ 770.1(c); 770.3.

* * * * *

[FR Doc. 2026-21963 Filed 10-27-26; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 26-196; RM-12024; DA 26-1125; FR ID 373925]

Television Broadcasting Services Elko, Nevada

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document amends the Table of TV Allotments (table) of the Federal Communications Commission's (Commission) rules by substituting VHF channel 10 for UHF channel 20 at Elko, Nevada in response to a petition for rulemaking filed by Reno (KENV-TV) Licensee, Inc. (Licensee), the licensee of full power television station KENV-DT (KENV-DT or Station), Elko, Nevada. The Media Bureau (Bureau) previously granted a petition for rulemaking submitted by the Licensee to substitute UHF channel 20 for VHF channel 10 at Elko in the table, and subsequently granted a construction permit for its new channel. The Licensee states that it was unable to complete construction of the channel 20 facility by the deadline specified in the Station's construction permit. The Licensee filed the instant petition to amend the table to substitute VHF channel 10 for UHF channel 20 and allow KENV-DT to continue to operate on channel 10 at its licensed parameters and provide uninterrupted service to viewers. The staff engineering analysis finds that the proposal is in compliance with the Commission's principal community coverage and technical requirements, including the interference protection requirements. In support of its channel substitution request, the Licensee filed comments reaffirming its interest and stating that it commits to promptly take any and all steps that may be necessary to effectuate the channel substitution proposed in the petition. An individual commenter, Steven Quinn Singleton, also filed comments, which, for the reasons discussed in the *Report and Order* referenced below, the Bureau denied.

DATES: Effective October 28, 2026.

FOR FURTHER INFORMATION CONTACT:

Emily Harrison, Media Bureau, at Emily.Harrison@fcc.gov, (202) 418-1665; or Mark Colombo, Media Bureau, at Mark.Colombo@fcc.gov, (202) 418-7611.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 26-196; RM-

12024; DA 26-1125, adopted October 20, 2026, and released October 20, 2026. The proposed rule was published at 91 FR 51421 on August 10, 2026. The full text of this document is available online at <https://www.fcc.gov/edocs>.

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13. In addition, therefore, it does not contain any proposed information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601-612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622, in the table in paragraph (j), under Nevada, revise the entry for "Elko" to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(j) * * *

	Community	Channel No.
	* * * * *	
	Nevada	
Elko		10
	* * * * *	

* * * * *

[FR Doc. 2026-22034 Filed 10-27-26; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 648****[Docket No. 260209–0039; RTID 0648–XG163]****Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer From Virginia to New Jersey**

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the Commonwealth of Virginia is transferring a portion of its 2026 commercial summer flounder quota to the State of New Jersey. This adjustment to the 2026 fishing year quota is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2026 commercial quotas for Virginia and New Jersey.

DATES: Effective October 27, 2026, through December 31, 2026.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, Fishery Management Specialist, (978) 281–9336.

SUPPLEMENTARY INFORMATION:

Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.111. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102, and the final 2026 allocations were published on February 19, 2026 (91 FR 7896).

The final rule implementing amendment 5 to the FMP, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers or

combinations would not preclude the overall annual quota from being fully harvested; (2) the transfers address an unforeseen variation or contingency in the fishery; and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined that these three criteria have been met for the transfer approved in this notification.

Virginia is transferring 9,745 pounds (lb; 4,420 kilograms (kg)) of summer flounder to New Jersey through a mutual agreement between the states. This transfer was requested to repay landings made by an out-of-state permitted vessel under a safe harbor agreement. The revised summer flounder quotas for 2026 are: Virginia, 2,423,982 lb (1,099,500 kg); and New Jersey, 2,119,613 lb (961,440 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.102(c)(2)(i) through (iv), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempted from review under Executive Order 12866.

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

Dated: October 26, 2026.

Shannon Bettridge,

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

[FR Doc. 2026–22003 Filed 10–27–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 648****[Docket No. 241203–0308; RTID 0648–XG153]****Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer From New York to North Carolina**

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of New York is transferring a portion of their 2026 commercial bluefish quota to the State of North Carolina. This quota adjustment is

necessary to comply with the Atlantic Bluefish Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2026 commercial bluefish quotas for New York and North Carolina.

DATES: Effective October 27, 2026 through December 31, 2026.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, Fishery Management Specialist, (978) 281–9336.

SUPPLEMENTARY INFORMATION:

Regulations governing the Atlantic bluefish fishery are found in 50 CFR 648.160 through 648.167. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through Florida. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.162, and the final 2026 allocations were published on February 19, 2026 (91 FR 7896).

The final rule implementing amendment 1 to the FMP, as published in the **Federal Register** on July 26, 2000 (65 FR 45844), provided a mechanism for transferring bluefish commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can request approval to transfer or combine bluefish commercial quota under § 648.162(e). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers would not preclude the overall annual quota from being fully harvested; (2) the transfers address an unforeseen variation or contingency in the fishery; and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined these criteria have been met for the transfers approved in this notification.

New York is transferring 200,000 pounds (lb) (90,718 kilograms (kg)) of Atlantic bluefish to North Carolina through mutual agreement of the states. This transfer was requested to ensure North Carolina would not exceed its 2026 state quota. The revised bluefish quotas for 2026 are: New York, 596,248 lb (270,454 kg); and North Carolina, 1,943,521 lb (881,566 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 648.162(e)(1)(i) through (iii), which was

issued pursuant to section 304(b), and is exempted from review under Executive Order 12866.

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

Dated: October 26, 2026.

Shannon Bettridge,

Acting Director, Office of Sustainable

Fisheries, National Marine Fisheries Service.

[FR Doc. 2026-22007 Filed 10-27-26; 8:45 am]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 91, No. 207

Wednesday, October 28, 2026

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2026-11818; Project Identifier MCAI-2026-00490-R]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2013-01-05, which applies to certain Airbus Helicopters (Eurocopter France) Model AS350B3 and EC130B4 helicopters. AD 2013-01-05 requires revising the Limitations section of the rotorcraft flight manual (RFM) supplement to reduce the starter generator operating current to 180 amperes (amps) and installing a placard in the instrument panel to indicate the revised limitation. Since the FAA issued AD 2013-01-05, the manufacturer determined the applicability needs to be revised to add helicopters equipped with certain part numbered starter generators and to remove helicopters with certain engines installed. This proposed AD would require revising the Limitations section of the RFM supplement of the existing RFM for the helicopter, to reduce the starter generator operating current to 180 amps and installing a placard in the instrument panel indicating the revised limitation. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by December 14, 2026.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Fax:* (202) 493-2251.

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

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

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2026-11818; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI) any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Airbus Helicopter material identified in this proposed AD, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641-0000 or (800) 232-0323; fax: (972) 641-3775; website: airbus.com/en/products-services/helicopters/hcare-services/airbusworld.

- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

FOR FURTHER INFORMATION CONTACT: Michael Yeshiambel, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946-4133; email: michael.m.yeshiambel@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under **ADDRESSES**. Include "Docket No. FAA-2026-11818; Project Identifier MCAI-2026-00490-R" at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing

date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Michael Yeshiambel, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2013-01-05, Amendment 39-17319 (78 FR 7641, February 4, 2013) (AD 2013-01-05), for certain Airbus Helicopters (Eurocopter France) Model AS350B3 and EC130B4 helicopters. AD 2013-01-05 was prompted by an MCAI originated by the European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union. EASA issued EASA AD 2006-0337, dated November 7, 2006, (EASA AD 2006-0337) to correct an unsafe condition identified as excessive power consumption of the starter generator, which reduces the engine surge margin and could result in engine failure.

AD 2013-01-05 requires revising the Limitations section of the RFM

supplement 29 to reduce the maximum current of the starter generator to 180 amps and installing a placard on the instrument panel below the vehicle engine multifunction display indicating the starter generator reduced limitation: “MAXIMUM CONTINUOUS GENERATOR LOAD = 180A” The FAA issued AD 2013–01–05 to prevent the engine surge margin being reduced, which can result in engine failure and loss of control of the helicopter.

Actions Since AD 2013–01–05 Was Issued

Since the FAA issued AD 2013–01–05, EASA superseded EASA AD 2006–0337 and issued EASA AD 2026–0089, dated May 7, 2026 (EASA AD 2026–0089) (also referred to as the MCAI). The MCAI states that the manufacturer revised the applicability to add starter generators having part number 200SGL130Q–4 and to remove certain helicopters equipped with an ARRIEL 2D engine.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–11818.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Airbus Alert Service Bulletin (ASB) AS350 No. 01.00.57 Revision 2 and Airbus ASB EC130 No. 04A002 Revision 2 and, both dated April 15, 2026, which specify procedures for installing a placard on the instrument panel below the Vehicle Engine Multifunction Display (VEMD).

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

FAA’s Determination

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this

State of Design Authority, that authority has notified the FAA of the unsafe condition described in the material referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the Limitations section of the RFM supplement of the existing RFM for the helicopter and installing a placard in the instrument panel to indicate the revised limitation.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 781 helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Install placard	1 work-hour × \$85 per hour = \$85	\$228	\$313	\$244,453
Revise RFM supplement	1 work-hour × \$85 per hour = \$85	0	85	66,385

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or

on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by:
 - a. Removing Airworthiness Directive 2013–01–05, Amendment 39–17319 (78 FR 7641, February 4, 2013); and
 - b. Adding the following new airworthiness directive:

Airbus Helicopters: Docket No. FAA–2026–11818; Project Identifier MCAI–2026–00490–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 14, 2026.

(b) Affected ADs

This AD replaces AD 2013–01–05, Amendment 39–17319 (78 FR 7641, February 4, 2013) (AD 2013–01–05).

(c) Applicability

This AD applies to Airbus Helicopters Model AS350B3 helicopters, except those equipped with an ARRIEL 2D engine, and all Model EC130B4 helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 2420, AC generation system.

(e) Unsafe Condition

This AD was prompted by the determination that the power drawn by the engines from certain starter generators is

above the declared consumption capacity. The FAA is issuing this AD to prevent the engine surge margin being reduced. The unsafe condition, if not addressed, could result in an engine failure and loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

For helicopters with a starter generator having part number (P/N) 200SGL130Q or P/N 200SGL130Q-4 installed, within the next 100 hours time-in-service after the effective date of this AD, accomplish the following:

(1) Revise Paragraph 2, Limitations, of the rotorcraft flight manual (RFM) supplement 29, page 1 of the existing RFM for the helicopter using pen and ink, reduce the maximum current of the starter generator to 180 amps Max. continuous.

(2) Install a placard, indicating the starter generator reduced limitation: "MAXIMUM CONTINUOUS GENERATOR LOAD = 180A" in accordance with Airbus Helicopters Alert Service Bulletin (ASB) AS350 No. 01.00.57, or Airbus Helicopters ASB EC130 No. 04A002 both Revision 2 and dated April 15, 2026, as applicable.

(h) Parts Installation Prohibition

As of the effective date of this AD, do not install starter generator part number (P/N) 200SGL130Q or P/N 200SGL130Q-4 on any helicopter, unless the actions in paragraph (g) of this AD are accomplished.

(i) No Reporting Requirement

Although the material referenced in this AD specifies to submit certain information to the manufacturer, this AD does not require that action.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Additional Information

For more information about this AD, contact Michael Yeshiambel, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (316) 946-4134; email: michael.m.yeshiambel@faa.gov.

(l) Material Incorporated by Reference

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

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

(i) Airbus Helicopters Alert Service Bulletin (ASB) AS350 No. 01.00.57 Revision 2, dated April 15, 2026.

(ii) Airbus Helicopters ASB EC130 No. 04A002 Revision 2, dated April 15, 2026.

(3) For Airbus Helicopters material identified in this AD, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone: (972) 641-0000 or (800) 232-0323; fax: (972) 641-3775; website: airbus.com/en/products-services/helicopters/hcare-services/airbusworld.

(4) You may view this material at FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

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

Issued on October 23, 2026.

Steven W. Thompson,

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

[FR Doc. 2026-21932 Filed 10-27-26; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG-2026-1152]

RIN 1625-AA08

Special Local Regulation; Port Miami Main Shipping Channel, Miami FL

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary special local regulation (SLR) for certain navigable waters of the Miami Shipping Channel offshore of Port Miami, Miami, FL in connection with the E1 Miami Grand Prix. The SLR is needed to protect personnel, vessels, and the marine environment from potential hazards created by high-speed powerboat racing. This proposed rulemaking would prohibit persons and vessels from being in or loitering around the regulated area unless specifically authorized by the Captain of the Port, Sector Miami. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before November 4, 2026.

ADDRESSES: To submit comments and view available documents, go to the Federal Docket Management System at <https://www.regulations.gov> and search for USCG-2026-1152.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rule, contact MST2 Elliot Cortes Waterways Management Division, U.S. Coast Guard; telephone 786-295-9051, or email SectorMiamiWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background and Authority

On July 22, 2026, Electric Sea Racing Limited notified the Coast Guard that it will be conducting the E1 Miami Grand Prix race on November 11, 2026, from 8 a.m. to 2 p.m., November 12, 2026, from 8 a.m. to 3:30 p.m., and November 13 through November 14, 2026, from 8 a.m. to 2 p.m. The race will take place in the Main Shipping Channel, offshore of Port Miami, Miami, FL, and involve approximately 12 electric high-speed powerboats 24 feet in length with no more than 5 racing at a time.

The Captain of the Port Miami (COTP) is issuing this Special Local Regulation (SLR) under the authority in 46 U.S.C. 70041. The purpose of this rulemaking is to protect event participants, spectators, and vessels on certain navigable waters of the Main Shipping Channel, offshore of Port Miami, Miami, FL before, during, and after the scheduled event.

III. Discussion of the Proposed Rule

This proposed rule would establish a special regulated area on November 11, 2026, from 8 a.m. to 2 p.m., November 12, 2026, from 8 a.m. to 3:30 p.m., and November 13 through November 14, 2026, from 8 a.m. to 2 p.m. Designated times for public transit through the regulated area on November 11, 2026, will be from 10 a.m. to 10:30 a.m., on November 12, 2026, from 11:35 a.m. to 11:55 a.m., November 13-14, 2026, from 11:10 a.m. to 11:50 p.m., and again from 12:10 p.m. to 12:40 p.m. The regulated area would cover all navigable waters within the Port Miami Main Shipping Channel beginning offshore from Terminal F and continuing northwest to

approximately 400 meters offshore from the Kaseya Center. The regulated area extends approximately 1 mile in length. No vessel or person will be permitted to enter the regulated area outside of the one designated window on November 11 and 12, 2026, and two designated windows on November 13 and 14, 2026, without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Impact on Small Entities

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

Vessel traffic will be able to safely transit around this regulated area. This regulation will only impact a small area for a few hours. The enforcement period is during a time when vessel traffic is normally low. In addition, the Coast Guard will issue a Broadcast Notice to Mariners via VHF FM marine channel 16, which will allow small entities to adjust their transit plans, and the rule allows vessels to request permission to enter the regulated area from the COTP or designated representative.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

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

section. Small businesses may send comments to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards by calling 1–888–REG–FAIR (1–888–734–3247).

B. Collection of Information

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

C. Federalism and Indian Tribal Governments

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

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

D. Unfunded Mandates Reform Act

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

E. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment.

This proposed rule is a special regulated area. It is categorically excluded from further review under paragraph L61.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material

received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Docket Management System at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2026–1152 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in the docket. To view available documents, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. We will post public comments in our online docket. Additional information is on the <https://www.regulations.gov> Frequently Asked Questions web page.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 100

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T07–1152 to read as follows:

§ 100.T07–1152 Special Local Regulation; Port Miami Main Shipping Channel, FL.

(a) *Location.* This special local regulation applies to the following regulated area: All waters of the Port Maimi Main Shipping Channel, from

surface to bottom, encompassed by a line connecting the following points beginning at 25°0'47" N, thence to 80°10'42" N, thence to 25°0'47" N, 80°10'44" W, thence to 25°0'47" N, 80°10'48" W, thence to 25°46'55" N, 80°10'48" W, thence to 25°46'44" N, 80°10'22" W, thence to 25°46'50" N, 80°10'18" W and along the shoreline back to the beginning point. These coordinates are based on the WGS 84.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) Sector Miami in the enforcement of the regulated area. *Participant* means all persons and vessels registered with the event sponsor as a participant in the race.

(c) *Regulations.* (1) All non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the Captain of the Port Miami or their designated representative. No vessel traffic shall loiter within the intercoastal waterway and shall maintain course and speed.

(2) To seek permission to enter, contact the COTP or the COTP's representative on VHF-FM channel 16 or by telephone at (833) 642-7271. Those in the special regulated area must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) The COTP will provide notice of the regulated area through advanced notice via broadcast notice to mariners and by on-scene designated representatives.

(d) *Enforcement periods.* This section will be enforced on November 11, 2026, from 8 a.m. to 2 p.m., November 12, 2026, from 8 a.m. to 3:30 p.m., and November 13 through November 14, 2026, from 8 a.m. to 2 p.m.

F.J. Florio,

Captain, U.S. Coast Guard, Captain of the Port Sector Miami.

[FR Doc. 2026-21949 Filed 10-27-26; 8:45 am]

BILLING CODE 9110-04-P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2026-4]

Exemptions To Permit Circumvention of Access Controls on Copyrighted Works

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Copyright Office is conducting the tenth triennial rulemaking proceeding under the Digital Millennium Copyright Act ("DMCA"), concerning temporary exemptions to the DMCA's prohibition against circumvention of technological measures that control access to copyrighted works. Having carefully considered the petitions for new and renewal exemptions and comments received in response to the June 9, 2026 Notification of Inquiry, the Office announces the Register's intention to recommend all but one of the existing exemptions for renewal, and initiates three rounds of public comment on newly proposed exemptions. Comments submitted may not exceed twenty-five pages per class, excluding documentary evidence.

DATES: Initial written comments, along with any documentary or multimedia evidence, from proponents and other members of the public who support the adoption of a proposed exemption, as well as those that neither support nor oppose an exemption but seek to share pertinent information, are due December 7, 2026. Written response comments, along with any documentary or multimedia evidence, from those who oppose the adoption of a proposed exemption are due February 22, 2027. Written reply comments from supporters of a proposal and parties that neither support nor oppose a proposal are due March 22, 2027.

ADDRESSES: The Copyright Office is using the *regulations.gov* system for the submission and posting of comments in this proceeding. All comments are to be submitted electronically through *regulations.gov*. The Office is accepting two types of comments. First, commenters who wish briefly to express general support for or opposition to a proposed exemption may submit such comments electronically by typing into the comment field on *regulations.gov*. Second, commenters who wish to provide a fuller legal and evidentiary basis for their position may upload a

Word or PDF document, but such longer submissions must be completed using the long comment form provided on the Office's website at <https://www.copyright.gov/1201/2027>. Specific instructions for submitting comments, including multimedia evidence that cannot be uploaded through *regulations.gov*, are available at <https://www.copyright.gov/1201/2027/comment-submission/>. If a commenter cannot meet a particular submission requirement, please contact the Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT:

Rhea Efthimiadis, Assistant to the General Counsel, by email at USCOGeneralCounsel@copyright.gov or by telephone at (202) 707-8350.

SUPPLEMENTARY INFORMATION: On June 9, 2026, the U.S. Copyright Office ("Office") initiated the tenth triennial section 1201 rulemaking by publishing a Notification of Inquiry ("NOI") and requesting petitions to renew current exemptions, comments responding to the renewal petitions, and petitions for newly proposed exemptions.¹ In response, the Office received 43 renewal petitions, three comments supporting renewal of an exemption, and eight comments opposing renewal of an exemption.² In addition, the Office received 25 petitions for new exemptions or for expansion of current exemptions.

This Notice of Proposed Rulemaking ("NPRM") summarizes the renewal petitions and states which exemptions the Register of Copyrights ("Register") intends to recommend for renewal without requiring petitioners to further develop the administrative record. Separately, this NPRM outlines the proposed classes for new exemptions for which the Office is initiating three rounds of public comment, including the one meaningfully opposed renewal petition that the Office will consider as a new petition.

I. Standard for Evaluating Proposed Exemptions

As the NOI explained, before the Register can recommend a temporary

¹ 91 FR 34795 (June 9, 2026) ("NOI").

² Renewal petitions, comments in response to renewal petitions, and petitions for new exemptions are available at <https://www.copyright.gov/1201/2027/>. References to renewal petitions and comments are by party name (abbreviated where appropriate) and a brief identification of the previously granted exemption, followed by either "Renewal Pet.," "Supp." (for comments supporting an exemption), or "Opp." (for comments opposing an exemption). References to petitions for new exemptions are by party name (abbreviated where appropriate), the Office's proposed class number, and "Pet."

exemption from the prohibition on circumvention, the record must establish that “persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the [anti-circumvention] prohibition . . . in their ability to make noninfringing uses under [title 17] of a particular class of copyrighted works.”³ When defining a “class of copyrighted works,” the Office generally uses the categories of works in 17 U.S.C. 102 as a starting point and then refines the class by other criteria, such as the technological protection measures (“TPMs”) used, distribution platforms, and types of uses or users.⁴

In evaluating the evidence, the Register weighs the statutory factors in section 1201(a)(1)(C): “(i) the availability for use of copyrighted works; (ii) the availability for use of works for nonprofit archival, preservation, and educational purposes; (iii) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research; (iv) the effect of circumvention of technological measures on the market for or value of copyrighted works; and (v) such other factors as the [Register] considers appropriate.”⁵ After the Office develops a comprehensive administrative record, the Register makes a recommendation to the Librarian of Congress (“Librarian”) concerning whether exemptions are warranted based on that record.

In considering whether to recommend an exemption consistent with the statutory text, the Register considers the question: “*Are users of a copyrighted work adversely affected by the prohibition on circumvention in their ability to make noninfringing uses of a class of copyrighted works, or are users likely to be so adversely affected in the next three years?*”⁶ This inquiry breaks down into the following elements:

- Does the proposed class include at least some works protected by copyright?
- Are the uses at issue likely noninfringing under title 17?
- Are users currently, or likely to be, adversely affected in their ability to make such noninfringing uses during the next three years?⁷
- Is the statutory prohibition on circumventing access controls the cause of the adverse effects?⁸

To determine whether a proposed use is likely to be noninfringing, the Register considers the Copyright Act and relevant judicial precedents.⁹ When considering whether such uses are being adversely impacted by the prohibition on circumvention, the rulemaking focuses on “distinct, verifiable, and measurable impacts” compared to “*de minimis* impacts.”¹⁰ The Register examines the administrative record as a whole to consider whether the preponderance of the evidence shows that the conditions for granting an exemption have been met.¹¹

⁷ This element is analyzed in reference to section 1201(a)(1)(C)’s five statutory factors.

⁸ Section 1201 Study at 115–27.

⁹ *Id.* at 115–17. While controlling precedent directly on point is not required to justify an exemption, there is no “rule of doubt” favoring an exemption when it is unclear that a particular use is fair or otherwise noninfringing. *See* U.S. Copyright Office, Section 1201 Rulemaking: Sixth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 15 (2015) (“2015 Recommendation”), <https://cdn.loc.gov/copyright/1201/2015/registers-recommendation.pdf>. The rulemaking also generally “is not an appropriate venue for breaking new ground in fair use jurisprudence.” U.S. Copyright Office, Section 1201 Rulemaking: Eighth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 10–11 (2021) (“2021 Recommendation”), https://cdn.loc.gov/copyright/1201/2021/2021_Section_1201_Registers_Recommendation.pdf (quoting Section 1201 Study at 116–17).

¹⁰ Commerce Comm. Report at 37; *see also* Staff of H. Comm. on the Judiciary, 105th Cong., Section-by-Section Analysis of H.R. 2281 as Passed by the United States House of Representatives on August 4th, 1998, at 6 (Comm. Print 1998) (using the equivalent phrase “substantial adverse impact”); *see also, e.g.*, Section 1201 Study at 119–21 (discussing same and citing application of this standard in five prior rulemakings).

¹¹ *See* 17 U.S.C. 1201(a)(1)(C) (asking whether users “are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition [on circumvention] in their ability to make noninfringing uses” (emphasis added)); Section 1201 Study at 111–12; *see also* *Sea Island Broad. Corp. v. FCC*, 627 F.2d 240, 243 (D.C. Cir. 1980) (noting that “[t]he use of the ‘preponderance of evidence’ standard is the traditional standard in civil and administrative proceedings”); 70 FR 57526, 57528 (Oct. 3, 2005); 2021 Recommendation at 7–8; U.S. Copyright Office, Section 1201 Rulemaking: Seventh Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Acting Register of Copyrights 13 (2018) (“2018

II. Review of Petitions To Renew Existing Exemptions

In this proceeding, the Office is again using the streamlined process, first adopted in the seventh triennial rulemaking, for the Register’s recommendations of renewal of exemptions previously issued by the Librarian.¹² As the Office explained in its 2017 policy study, the “Register must apply the same evidentiary standards in recommending the renewal of exemptions as for first-time exemption requests,” and the statute requires that “a determination must be made specifically for each triennial period.”¹³ The Office further determined that “the statutory language appears to be broad enough to permit determinations to be based upon evidence drawn from prior proceedings, but only upon a conclusion that this evidence remains reliable to support granting an exemption in the current proceeding.”¹⁴ The Office has employed this process in each subsequent triennial rulemaking.

Renewal petitions must request readoption of exemptions as currently formulated, without modification. Petitions should support a determination by the Register that, due to a lack of legal, marketplace, or technological changes, the factors that led her to recommend adoption of the exemption in the prior rulemaking remain a reliable basis for the adoption of the exemption.¹⁵ To the extent that a renewal petition proposes uses beyond the current exemption or language that varies from the exemption as currently enacted, the Office disregards those portions of the petition for purposes of considering the renewal of the exemption, and asks only whether the petition provides sufficient information

Recommendation”), https://cdn.loc.gov/copyright/1201/2018/2018_Section_1201_Acting_Registers_Recommendation.pdf; 2015 Recommendation at 13–14; U.S. Copyright Office, Section 1201 Rulemaking: Fifth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 6 (2012) (“2012 Recommendation”), https://cdn.loc.gov/copyright/1201/2012/Section_1201_Rulemaking_Recommendation.pdf; U.S. Copyright Office, Section 1201 Rulemaking: Second Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 19–20 (2003) (“2003 Recommendation”), <https://cdn.loc.gov/copyright/1201/docs/registers-recommendation.pdf>.

¹² 2018 Recommendation at 17, 19, 22 (explaining the streamlined renewal process and how the Office was able to recommend renewal of all previously granted exemptions, since each then-current exemption was renewed and not meaningfully contested).

¹³ Section 1201 Study at 142, 145.

¹⁴ *Id.* at 143.

¹⁵ *See id.* at 143–44.

³ 17 U.S.C. 1201(a)(1)(C).

⁴ *See* U.S. Copyright Office, Section 1201 Rulemaking: Ninth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 13–14 (2024) (“2024 Recommendation”), https://www.copyright.gov/1201/2024/2024_Section_1201_Registers_Recommendation.pdf; U.S. Copyright Office, Section 1201 of Title 17, at 26, 108–10 (2017) (“Section 1201 Study”), <https://www.copyright.gov/policy/1201/section-1201-full-report.pdf>; *see also* H.R. Rep. No. 105–551, pt. 2, at 38 (1998) (“Commerce Comm. Report”) (“The Committee intends that the ‘particular class of copyrighted works’ be a narrow and focused subset of the broad categories of works of authorship than is identified in Section 102 of the Copyright Act (17 U.S.C. [section] 102).”).

⁵ 17 U.S.C. 1201(a)(1)(C).

⁶ Section 1201 Study at 114.

to warrant renewal of the exemption in its current form.

In response to its current NOI, the Office received petitions to renew every existing exemption. Each of the forty-three renewal petitions included a summary of the basis for the continuing need and justification for the exemption. Each petitioner also signed a declaration stating that, to the best of their personal knowledge, there has not been any material change in the facts, law, or other circumstances set forth in the prior rulemaking record such that renewal of the exemption would not be justified. This sworn declaration also includes a statement that, based on their personal knowledge and experience, petitioners believe that if the exemption were not renewed, users would be diminished in their ability to make use of the works at issue.¹⁶

The Office received eleven comments in response to the renewal petitions, three of which support renewal of specific exemptions. Eight comments oppose certain aspects of the renewal petitions.¹⁷

As detailed below, after reviewing the petitions for renewal and comments in response, the Office finds that it has received a sufficient petition for each of the existing exemptions. The Office finds meaningful opposition to renewal of one exemption (the current medical device repair exemption); it will not grant this exemption through the streamlined renewal process but will instead allow interested parties to develop the record further so that it can be considered as a new proposed exemption in the regular rulemaking process. The Register intends to recommend readoption of each of the other existing exemptions in their current forms.

A. Audiovisual Works—Criticism and Comment—Filmmaking

International Documentary Association and Kartemquin Educational Films (collectively “Joint Filmmakers”) jointly petition to renew the exemption for motion pictures¹⁸ for

uses in documentary films or other films where the use is a parody or for a biographical or historically significant nature (codified at 37 CFR 201.40(b)(1)(i)(A)).¹⁹ No comments were filed opposing renewal.

Joint Filmmakers represent thousands of independent filmmakers across the nation and have participated in every triennial rulemaking since 2008. They state that TPMs such as encryption continue to prevent filmmakers from accessing needed material, and that this is “especially true for the kind of high fidelity motion picture material filmmakers need to satisfy both distributors and viewers.”²⁰ Petitioners state their firsthand knowledge that filmmakers have found it necessary to rely on this exemption and will continue to do so.²¹

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

B. Audiovisual Works—Criticism and Comment—Noncommercial Videos

The Organization for Transformative Works (“OTW”) petitions to renew the exemption for motion pictures for use in noncommercial videos (codified at 37 CFR 201.40(b)(1)(i)(B)).²² OTW, which has advocated for the noncommercial video exemption in past triennial rulemakings, states it has heard from “a number of noncommercial remix artists” who have used the exemption in the past and anticipate needing to use it in the future as well as the increasing cultural and political importance of “fan edits.”²³

OTW states that “creators continue to make video remixes using DVD and Blu-Ray source[s]” for several reasons, such as engaging in “valuable commentary” and that the “fundamental conditions surrounding video remix have not changed” in the preceding three-year period.²⁴ No comments were filed opposing renewal of the exemption as currently formulated.

The Office did, however, receive opposition to OTW’s renewal petition to the extent it seeks to modify the regulatory language of this exemption. As in the previous proceeding, OTW’s renewal petition proposes the Office

“us[e] the relatively simple language defining the exempted class from the 2008 rulemaking,” rather than the exact language in the current exemption, which was adopted in the 2021 rulemaking.²⁵ The Entertainment Software Association, Motion Picture Association, and Recording Industry Association of America (collectively “Joint Creators”) jointly oppose OTW’s petition to the extent that it requests modification of the exemption’s language, arguing the request constitutes an expansion and should therefore be properly submitted as a petition for a new exemption.²⁶ The Office agrees. Such a modification cannot be granted via the streamlined exemption renewal procedure and must instead be petitioned for as a new exemption.²⁷ OTW did not submit a separate new exemption petition for its proposed modifications. Therefore, OTW’s renewal petition will be considered only to the extent that it requests readoption of the current exemption; its proposed modifications cannot be considered in this triennial proceeding.

Based on the information provided in the renewal petition and the lack of meaningful opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

C. Audiovisual Works—Criticism and Comment—Multimedia E-Books

Authors Alliance and independent film producer and author, Bobette Buster, filed a joint petition to renew the exemption for the use of motion picture excerpts in nonfiction multimedia e-books (codified at 37 CFR 201.40(b)(1)(i)(C)).²⁸ No comments were filed opposing renewal.

Petitioners point to Professor Buster’s continuing work authoring film education e-books, which rely on the “essential” use of high-resolution video that would not be available “without the circumvention of technological protection measures.”²⁹ In addition to the e-book series titled “Deconstructing Master Filmmakers” discussed in previous rulemakings, Professor Buster

¹⁶ 82 FR 29804, 29806 (June 30, 2017).

¹⁷ See, e.g., Entertainment Software Association, Motion Picture Association & Recording Industry Association of America (collectively “Joint Creators”) Noncom. Videos Opp.; Association of American Publishers (“AAP”) TDM Opp.; Alliance for Automotive Innovation (“Auto Innovators”) Vehicle Repair Opp.; Auto Innovators Vehicle Data Opp.; Advance Medical Technology Association (“AdvaMed”) Medical Device Repair Opp. #1; AdvaMed Medical Device Repair Opp. #2; Joint Creators Medical Device Repair Opp.; Philips North America, LLC (“Philips”) Medical Device Repair Opp.

¹⁸ Unless otherwise noted, all references to motion pictures as a category include television programs and videos.

¹⁹ Joint Filmmakers Documentary Films Renewal Pet.

²⁰ *Id.* at 4.

²¹ *Id.*

²² OTW Noncom. Videos Renewal Pet.

²³ *Id.* at 4–5.

²⁴ *Id.*

²⁵ *Id.* at 6. OTW describes its requested change to the exemption language as “not . . . an expansion of the existing exemption, but a more understandable restatement.” *Id.*

²⁶ Joint Creators Noncom. Videos Opp. at 1–2.

²⁷ See NOI at 34797 (“Only petitions requesting renewal of current exemptions as currently written in the *Code of Federal Regulations*, without modification, may be considered under the streamlined renewal procedure.”).

²⁸ Buster & Authors Alliance Nonfiction Multimedia E-Books Renewal Pet.

²⁹ *Id.* at 4.

newly references her lecture series titled “How to Tell Your Story Well,” “What’s the Big Idea,” and “Satire and the Shaping of American Culture” and states that she uses the lectures’ source material—“particularly film clips that are the subject of this exemption”—in e-book projects that are part of this “broader work in deconstructing feature-length films in-depth.”³⁰ Such contemporary evidence of the ongoing need for the exemption combined with petitioners’ participation in the last four triennial rulemakings, provide a sufficient basis for renewal of the current exemption.³¹

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

D. Audiovisual Works—Criticism and Comment—Universities and K–12 Educational Institutions

Peter Decherney, John Jackson, Sarah Banet-Weiser, Library Copyright Alliance (“LCA”), and Society for Cinema and Media Studies (“SCMS”) (collectively “Joint Educators”) jointly petition to renew the exemption for the use of motion picture excerpts for educational purposes by college and university faculty, students, or employees, or K–12 educators and students (codified at 37 CFR 201.40(b)(1)(ii)(A)).³² Brigham Young University-Idaho (“BYU-Idaho”) filed a comment in support of renewal,³³ and no comments opposing renewal were filed.

Joint Educators provide several contemporary examples of educators and students using film clips for educational purposes including class

presentations and coursework. Co-petitioner Decherney declares that he “continues to teach courses every semester that require[s] students to create video essay[s],” which are “piece[s] of video-based criticism or scholarship that makes an argument through the audiovisual medium itself” that are subsequently presented for comment and discussion.³⁴ Joint Educators also point to an increase of multimedia criticism in the classroom, with educators “treating film clips and other media not as illustrations of a written argument but as evidence and analytic tools in their own right,” and “build[ing] a lecture or seminar around close analysis of scenes from documentaries, news footage, or television dramas.”³⁵ In this rulemaking and through their participation in previous triennial rulemakings, petitioners have represented thousands of digital and literacy educators and/or members supporting educators and students. Joint Educators again suggest that the “entire field” of video essays or multimedia criticism “could not have existed in the United States without fair use and the 1201 educational exemption.”³⁶

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

E. Audiovisual Works—Criticism and Comment—Massive Open Online Courses (“MOOCs”)

Joint Educators also petition to renew the exemption for motion pictures for educational uses in MOOCs (codified at 37 CFR 201.40(b)(1)(ii)(B)).³⁷ No comments opposing renewal were filed, and BYU-Idaho filed a comment in support of renewal.³⁸

The petition states that instructors continue to rely on the exemption to “develop, provide, and improve MOOCs,” as well as increase the number of (and therefore access to) MOOCs, particularly in the field of film and media studies.³⁹ Joint Educators note the impact of Professor Decherney’s History of Hollywood class, which “offers close readings of Hollywood classics like” *King Kong* and

Casablanca and “analyzes digital special effects, sound design, and other elements of filmmaking”—reaching almost 80,000 students.⁴⁰ The petition also states that the exemption’s relevance and use has flourished since the COVID–19 pandemic and the “universal continuing shift of our education systems to online learning,” which has resulted in increased MOOCs offerings and enrollment.⁴¹

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

F. Audiovisual Works—Criticism and Comment—Digital and Media Literacy Programs

LCA petitions to renew the exemption for motion pictures for educational uses in nonprofit digital and media literacy programs offered by libraries, museums, and other nonprofits (codified at 37 CFR 201.40(b)(1)(ii)(C)).⁴² No comments opposing renewal were filed, and BYU-Idaho filed a comment in support of renewal.⁴³

LCA, whose member associations comprise “over 100,000 libraries in the United States,” states in its petition that librarians, museums, and other nonprofit entities across the country have relied on the current exemption and will continue to do so for their digital and media literacy programs.⁴⁴ Noting that LCA has participated in every previous triennial rulemaking, including several related to this particular exemption, the petition states that LCA has a high degree of familiarity with the relevant standards.⁴⁵ It states that libraries, museums, and other nonprofit entities “will continue to need to circumvent technological protections so as to enable noninfringing uses of motion pictures in their digital and literacy programs.”⁴⁶

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

³⁰ *Id.* (explaining that Professor Buster “uses extracts of [her popular] lecture[] series] as the basis of digital publications, which include[] projects to create ebooks featuring source materials from [those] lectures, particularly film clips that are the subject of this exemption”).

³¹ See NOI at 34797 n.19; see also 88 FR 72013, 72016 n.35 (Oct. 19, 2023) (same).

³² Joint Educators AV Educ. Renewal Pet.

³³ BYU-Idaho AV Educ. Supp. BYU-Idaho filed a single comment in support of “renewal of the current exemption in 37 [CFR section] 201.40(b)(1) for audiovisual works used for educational purposes by college and university faculty and students.” *Id.* at 1. The Office understands this comment to support the three exemptions codified at 37 CFR 201.40(b)(1)(ii). See *id.* (referencing 37 CFR 201.40(b)(1)(ii)(A)–(C)). BYU-Idaho’s comment also requests that the Office replace portions of the text of the current exemption for the purpose of clarification. *Id.* at 2–3. Such a request is properly submitted as a petition for a new exemption during the petition phase of the rulemaking process and is therefore not considered here. See NOI at 34797.

³⁴ Joint Educators AV Educ. Renewal Pet. at 4.

³⁵ *Id.*

³⁶ *Id.*; see 2024 Joint Educators AV Educ. Renewal Pet. at 3 (same).

³⁷ Joint Educators AV Educ. MOOCs Renewal Pet.

³⁸ BYU-Idaho AV Educ. Supp.

³⁹ Joint Educators AV Educ. MOOCs Renewal Pet. at 4.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² LCA AV Educ. Nonprofits Renewal Pet.

⁴³ BYU-Idaho AV Educ. Supp.

⁴⁴ LCA AV Educ. Nonprofits Renewal Pet. at 4.

⁴⁵ *Id.*

⁴⁶ *Id.*

G. Audiovisual Works—Captioning and Audio Description

The Association on Higher Education and Disability (“AHEAD”), LCA, and KeriAnn Hollerud jointly petition to renew the exemption for motion pictures for the provision of captioning and/or audio description by disability services offices or similar units at educational institutions for students, faculty, or staff with disabilities (codified at 37 CFR 201.40(b)(2)).⁴⁷ No comments were filed opposing renewal.

Petitioners assert that students with disabilities continue to rely on the exemption, stating that disability services professionals and supporting entities, such as libraries, “have used the exemption to address the requests and concerns of students with disabilities in attendance at their respective educational institutions to create equitable educational experiences,” “ensur[ing] that students with disabilities have access to the same advantages as their peers in the pursuit of education.”⁴⁸ “Based on their regular interaction with those affected by the exemption,” petitioners believe that the circumstances justifying the exemption currently exist and will persist for the next three years.⁴⁹

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

H. Audiovisual Works—Preservation or Replacement—Library, Archives, and Museum

LCA petitions to renew the exemption for motion pictures for preservation or the creation of a replacement copy by an eligible library, archives, or museum (codified at 37 CFR 201.40(b)(3)).⁵⁰ No comments were filed opposing renewal.

LCA, which participated in the triennial rulemakings that granted the initial and renewal exemptions, states in its petition that “[c]ultural heritage institutions across the country have relied on the exemption . . . to make preservation and replacement copies of the motion pictures in their collections stored on DVDs and Blu-ray discs.”⁵¹ The petition further notes that many motion pictures in its over 100,000 member libraries’ collections “are

unavailable for purchase or streaming” or “continue to deteriorate,” demonstrating the need to engage in such preservation efforts.⁵²

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

I. Audiovisual Works—Text and Data Mining—Scholarly Research and Teaching

Authors Alliance and LCA jointly petition to renew the exemption for text and data mining (“TDM”) of motion pictures by researchers affiliated with a nonprofit institution of higher education, or at the direction of such researchers, for the purpose of scholarly research and teaching (codified at 37 CFR 201.40(b)(4)).⁵³ No comments were filed opposing renewal.

The petition reports that this “exemption has enabled ambitious research agendas that have resulted in published scholarship,” citing a study published in *PNAS* analyzing diversity in Hollywood and other ongoing projects.⁵⁴ “Many researchers are now actively relying on” the exemption for their research, including those at “large research-intensive institutions, such as Stanford University, UC Berkeley, the University of Chicago, [and] Dartmouth.”⁵⁵ Authors Alliance and LCA claim “an increasingly broad group of researchers from smaller and less research-intensive institutions” like Haverford College and Hofstra University “have expressed interest in using the new exemption.”⁵⁶

According to the petition, “academic researchers need to assemble and annotate their own research corpora,” and will continue to need to do so.⁵⁷ The petition further states that the relevant case law has not changed and although “[c]ommercially licensed text and data mining products continue to be made available to research institutions,” such products “do not allow researchers to license the full array of films needed to engage in the research they seek to do, and those works remain protected

from copying by” TPMs.⁵⁸ Finally, the petition notes that the exemption excludes compilations licensed for institutional TDM research.⁵⁹

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

J. Literary Works—Text and Data Mining—Scholarly Research and Teaching

Authors Alliance and LCA also jointly petition to renew the exemption for text and data mining of literary works distributed electronically, conducted by researchers affiliated with a nonprofit institution of higher education, for the purpose of scholarly research and teaching (codified at 37 CFR 201.40(b)(5)).⁶⁰ The Association of American Publishers (“AAP”) submitted a comment in opposition.

This petition parallels the petition for text and data mining of audiovisual works, submitted by the same joint petitioners. Petitioners, who have communicated with “well over a thousand researchers, librarians, and other academic faculty” as part of their outreach to digital humanities research communities, state these researchers are “now actively relying on the TDM exemption in their research.”⁶¹ Petitioners assert “[t]he exemption has contributed to the growing field of the digital humanities . . . [and] has enabled discrete research projects as well as the development of new research methods.”⁶² Acknowledging that “[c]ommercially licensed [TDM] products continue to be made available to research institutions,” petitioners nonetheless state that these products do not provide researchers access to the “full array of texts needed” to conduct their research.⁶³ Because researchers actively rely on the current exemption, and because “there are no material changes in facts, law, technology, or other circumstances that would justify failing to renew it,” petitioners seek to renew the exemption in this cycle.⁶⁴

AAP’s comment opposing renewal contends that the previous rulemaking

⁵² *Id.*

⁵³ Authors Alliance & LCA AV Text and Data Mining Renewal Pet.

⁵⁴ *Id.* at 4 (citing David Bamman et al., *Measuring Diversity in Hollywood Through the Large-Scale Computational Analysis of Film*, 121 Proc. Nat’l Acad. Sciences, no. 46 (Nov. 4, 2024), <https://doi.org/10.1073/pnas.2409770121>).

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ Authors Alliance & LCA LW Text and Data Mining Renewal Pet.

⁶¹ *Id.* at 4.

⁶² *Id.* (citing Digital Humanities 2025: Book of Abstracts (Gimena Riande et al. eds., 2025), <https://zenodo.org/records/19494802>).

⁶³ *Id.*

⁶⁴ *Id.*

⁴⁷ AHEAD, LCA & Hollerud Captioning Renewal Pet.

⁴⁸ *Id.* at 4.

⁴⁹ *Id.*

⁵⁰ LCA Preservation Renewal Pet.

⁵¹ *Id.* at 4.

record has become unreliable due to factual developments.⁶⁵ AAP first argues that market solutions for researchers to access large corpora of rights-cleared works have emerged in recent years, obviating the need for circumvention and undermining the finding in past rulemakings that researchers lack alternatives to circumvention.⁶⁶ AAP lists several services through which publishers offer their works for use in TDM research, stating that a “wide array of prominent nonprofit research institutions of higher education have already adopted [these services] as a library service to facilitate TDM research, including Columbia University, University of Washington, University of Chicago, Brown University, and University of Oxford.”⁶⁷ AAP also argues that the exemption has had the unintended consequence of contributing to the use of unlawfully acquired works for TDM, asserting that some researchers have scraped pirate sites for TDM research, and that “concerns that unprotected corpora created under the exemption will be siphoned off to train generative [artificial intelligence (‘AI’)] models” have been heightened.⁶⁸

The growth in licensed options for text and data mining that AAP describes is an important consideration to the extent that it obviates the need for the exemption.⁶⁹ While petitioners and opponents agree that such growth has occurred since the last triennial rulemaking proceeding, the evidence AAP provides relates only to a small subset of the works used for TDM research. Even with access to the new options AAP describes, researchers would not have access to the full array of works currently covered by the exemption in the absence of renewal. Accordingly, these developments do not show that the prior rulemaking record no longer reliably supports renewal. For instance, the record does not show that contemporary, in-copyright literary works (like mass market fiction) are now available for licensed TDM use. In 2021, the Register found that the research and teaching the TDM exemption supports can require this type of works: “But for the prohibition on circumvention, researchers would be able to perform TDM techniques on contemporary

literary works . . . and teach those techniques in their courses.”⁷⁰ Proponents explained that TDM research on literary works had “typically only been done on works that are in the public domain,”⁷¹ and that the inability to conduct TDM apart from public domain texts contributed to existing biases within the field.⁷² The Register also found that the offerings of digital libraries like HathiTrust “are insufficient to allow researchers to conduct [this] type of research” in part because of “substantial gaps in its collection,” which “contains a greater proportion of academic monographs than mass-market fiction.”⁷³ The inability to use contemporary literary works to teach engaging lessons on TDM was an issue that many academics raised.⁷⁴ The Register found that the new exemption would “enable professors to teach TDM techniques to students using contemporary, diverse, and inclusive works.”⁷⁵ In 2024, the Register found that the Copyright Clearance Center’s RightFind service, which licenses journal articles for text and data mining, was not a “serious alternative to circumvention . . . due to the relatively limited scope of the materials it licenses.”⁷⁶

AAP does not identify the works that the publisher and platform offerings it cites make available for TDM research. The services it describes—API access from Wiley, Springer Nature, and Elsevier—are offered by scholarly and scientific publishers. Their offerings are of the same nature as the journal article licensing the Register found inadequate for these TDM research uses in 2024,⁷⁷ although no doubt enormously powerful for mining the scientific, technical, and medical literature those publishers produce. The collection AAP describes most specifically, the twenty-five million pages of historical archival materials in History Vault that ProQuest recently added to its TDM Studio product,⁷⁸ does not supply what the prior record documented researchers could not obtain. The valuable addition of vast amounts of archival materials to

the scholarly and scientific platforms detailed by AAP still do not make these platforms adequate alternatives for large swaths of the research being conducted under this exemption.⁷⁹

AAP’s other arguments raise concerns about conduct that is outside of the scope of the exemption. While the Office understands the seriousness of unlawful acquisition and use of copyrighted works—and shares in AAP’s concern about such risks—the exemption is written to specifically exclude such conduct. To the extent there is any doubt, we reaffirm here that the exception does not permit or sanction these types of acts.

AAP’s comment does not provide support for its contention that the exemption is “providing inadvertent cover” for the use of unlawfully acquired literary works.⁸⁰ AAP’s single example, a project in which researchers in France downloaded millions of e-books from pirate sites, does not involve circumvention let alone rely on a 1201 exemption. The catalog the researchers released “reproduces no textual content from the underlying books.”⁸¹ Additionally, this project does not appear to satisfy the exemption’s requirement that works be “lawfully acquired and owned by the institution, or licensed to the institution without a time limitation on access,”⁸² as the researchers themselves describe their work as “harvesting and computing data from shadow libraries.”⁸³ AAP does not argue otherwise, and it does not contend that the project qualified for the exemption.⁸⁴

⁷⁹ See 2024 Recommendation at 88 (“credit[ing] proponents’ explanation that the licensing options identified by AAP are not suitable for the type of research at issue”).

⁸⁰ AAP LW Text and Data Mining Opp. at 6.

⁸¹ Antoine Mazières & Thierry Poibeau, *MajinBook: An Open Catalogue of Digitally Mediated World Literature*, 11 J. Cultural Analytics 2, 17 (2026), <https://culturalanalytics.org/article/id/1164/>. The researchers converted pirated e-books to text, matched them to Goodreads records, and released a catalog listing the matched books (not the text of the works). Additionally, the researchers state that they did not circumvent the only technological measures referenced—those on the Goodreads website. See *id.* at 18.

⁸² 37 CFR 201.40(b)(5)(i)(B).

⁸³ AAP LW Text and Data Mining Opp. at 6 (quoting Mazières & Poibeau, *supra* note 81 at 18).

⁸⁴ *Id.* & n.27. Nor do the French researchers suggest that the 1201 exemption applies to their work. Instead, they generally reference the exemption as one of several possible lenses through which to consider projects similar to their own. See *id.* (quoting Mazières & Poibeau, *supra* note 81 at 18) (asserting that “harvesting and computing data from shadow libraries as [they] did can be considered through the lens of several legal frameworks: In the EU, the above-mentioned ‘TDM exception’, and in the U.S., the fair use doctrine incorporated into the Copyright Act of 1976

Continued

⁶⁵ AAP LW Text and Data Mining Opp. at 1–2.

⁶⁶ *Id.* at 2–5.

⁶⁷ *Id.* at 3.

⁶⁸ *Id.* at 5–8.

⁶⁹ The exemption excludes from its scope compilations that were compiled specifically for TDM purposes. 37 CFR 201.40(b)(5)(i) (stating that the exemption involves “[l]iterary works, excluding . . . compilations that were compiled specifically for text and data mining purposes”).

⁷⁰ 2021 Recommendation at 117.

⁷¹ *Id.* at 104.

⁷² 2021 Authors Alliance/American Association of University Professors (“AAUP”)/LCA Class 7 Initial at 9 (quoting App. O at 2 (letter from Melanie Walsh)).

⁷³ 2021 Recommendation at 117–18 (citing evidence that HathiTrust has proportionally fewer romance and science fiction).

⁷⁴ See 2021 Authors Alliance/AAUP/LCA Class 7 Initial at 31, Apps. B–P.

⁷⁵ 2021 Recommendation at 120.

⁷⁶ 2024 Recommendation at 88.

⁷⁷ AAP LW Text and Data Mining Opp. at 3; see 2024 Recommendation at 88.

⁷⁸ AAP LW Text and Data Mining Opp. at 3.

AAP's suggestion that "unprotected corpora created under the exemption will be siphoned off to train generative AI models," also refers to risks outside the scope of the exemption.⁸⁵ As AAP acknowledges, circumventing TPMs to compile AI model training data sets is permitted by the exemption. The exemption requires research institutions to implement "effective security measures" to prevent non-exempted uses and to "limit[] access to the corpus to only" researchers at nonprofit institutions.⁸⁶ AAP does not identify any instances of the security measures protecting a corpus compiled under the exemption being breached or a corpus being used for training generative AI. This serious but unsubstantiated possibility therefore does not provide a basis for the Register to refuse to recommend renewing the exemption.

After reviewing the renewal petition, the opposition comment, and the record from the previous rulemakings, the Register concludes that the prior record provides a sufficient basis for renewal. Contrary to AAP's assertion, Authors Alliance and LCA state in their petition that "[c]ommercially licensed [TDM] products continue to be made available to research institutions" but "these licensed products do not allow researchers to license the full array of texts needed to engage in the research they seek to do."⁸⁷ Because the conditions that led to the adoption of this exemption are likely to continue during the next triennial period, the Register intends to recommend renewal.

K. Literary Works—Assistive Technologies

The American Council of the Blind ("ACB"), American Foundation for the Blind ("AFB"), and LCA (collectively "Accessibility Petitioners") jointly petition to renew the exemption for literary works or previously published musical works that have been fixed in the form of text or notation whose technological measures interfere with assistive technologies (codified at 37 CFR 201.40(b)(6)).⁸⁸ No comments were filed opposing renewal.

Petitioners advocate for individuals with print disabilities and have direct experience with the assistive technology

complemented by the recent Text and Data Mining exemption to the Digital Millennium Copyright Act (1998)."). The researchers, who describe themselves as "nonlegal scholars," go on to concede that the application of the cited frameworks was "beyond the scope" of their work. *Id.* at 18.

⁸⁵ *Id.* at 7.

⁸⁶ 37 CFR 201.40(b)(5)(i)(D)–(E).

⁸⁷ Authors Alliance & LCA LW Text and Data Mining Renewal Pet. at 4.

⁸⁸ Accessibility Petitioners Assistive Technologies Renewal Pet.

exemption, as they have participated in every proceeding in which this exemption has been considered. The petition asserts that individuals who are blind, visually impaired, or print disabled are significantly disadvantaged with respect to obtaining accessible e-book content because TPMs interfere with the use of assistive technologies.⁸⁹ Specifically, petitioners state that "many e-books have built-in security software that prevents purchasers and other third parties from utilizing them outside of publisher-designated e-book reader platforms" and that "[t]he availability of non-circumventing alternatives, such as audiobook and Braille versions provided by publishers, remains limited."⁹⁰ Petitioners also note that the record underpinning the exemption "has stood and been re-established in the past eight triennial reviews dating back to 2003" and that the "accessibility of e-books is frequently cited as a top priority" by its members.⁹¹

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

L. Literary Works—Medical Device Data

The Coalition of Medical Device Patients and Researchers ("Coalition") petition to renew the exemption covering access to patient data on medical devices or monitoring systems (codified at 37 CFR 201.40(b)(7)).⁹² No comments were filed opposing renewal.

The petition states that patients continue to need access to data output from their medical devices to manage their health and react to their medical data in real-time, which the current exemption facilitates.⁹³ In addition to noting their experience with the exemption through participation in past rulemakings, petitioners provided contemporary examples of the barriers to and need for obtaining access to their medical devices' data outputs.⁹⁴ One member attests that, without the exemption, he would be unable to access personal data recorded by his home life-support ventilator.⁹⁵ Another member describes how the manufacturer of her implanted

defibrillator has significantly reduced its U.S. presence over time, making it difficult to access representatives with the expertise required to retrieve health information from the device or to modify the device's operation to address her changing medical needs.⁹⁶

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

M. Computer Programs—Unlocking

The Recycled Materials Association ("ReMA") petitions to renew the exemption for computer programs that operate wireless devices, to allow connection of the device to an alternative wireless network ("unlocking") (codified at 37 CFR 201.40(b)(8)).⁹⁷ No comments were filed opposing renewal.

ReMA, with over 1,700 member companies that recycle, refurbish and repair electronic products, reports its members, who rely on the ability to unlock cellphones for re-purposing them, continue to receive wireless products locked to a particular wireless carrier.⁹⁸ Moreover, ReMA notes that the number of 5G-enabled device types has continued to grow—nearly tripling since the previous rulemaking; this means that there are many more types of devices that may require unlocking.⁹⁹ ReMA states that its members continue to acquire cell phones, tablets, and other wireless devices for reuse, but that wireless carriers still lock devices to prevent them from being used on other carriers.¹⁰⁰

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

N. Computer Programs—Jailbreaking

The Office received multiple petitions to renew the four exemptions that permit enabling electronic devices to interoperate with or to remove software

⁹⁶ *Id.*

⁹⁷ ReMA Unlocking Renewal Pet. In 2024, the Institute of Scrap Recycling Industries, Inc. ("ISRI") "rebranded itself and began operating under a new dba, the Recycled Materials Association (ReMA)." *Id.* at 4.

⁹⁸ *Id.* at 4–5.

⁹⁹ *Id.* at 4. ReMA has participated in these rulemaking proceedings "over multiple cycles." *Id.*

¹⁰⁰ *Id.* at 4–5.

applications (“jailbreaking”) (codified at 37 CFR 201.40(b)(9)–(12)).¹⁰¹ No comments opposing renewal were filed.

The renewal petitions provide evidence of the continuing need and justification for the four jailbreaking exemptions. Regarding smartphones and other portable mobile computing devices, EFF asserts that it “heard from many device users who currently rely on the jailbreaking exemption and anticipate continuing to rely on the exemption in the future” for uses such as installing an alternative operating system, maintaining functionality of older devices, and installing custom applications developed outside of official app store processes.¹⁰² As to smart televisions, SFC states that “at least one Smart TV platform (SmartCast) ship[s] to the consumer in a ‘locked’ format, which prevent[s] users from loading third-party software to enable interoperability.”¹⁰³ As to voice assistant devices, EFF explains some users of voice assistant devices wish to expand the devices’ functionality by installing updated software, or by installing “privacy-first” software alternatives to limit personal data collection.¹⁰⁴ Lastly as to routers, SFC states that based on its observations, there is a continued need to install alternative firmware and security updates to improve reliability, enable new functionality, and install licensed software on networking devices.¹⁰⁵

Based on the information provided in the renewal petitions and the lack of opposition, the Office concludes that the conditions that led to the adoption

of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

O. Computer Programs—Repair of Motorized Land Vehicles, Marine Vessels, or Mechanized Agricultural Vehicles or Vessels

Both MEMA, The Vehicle Suppliers Association (“MEMA”) and the Specialty Equipment Market Association (“SEMA”) file petitions to renew the exemption for computer programs that control motorized land vehicles, marine vessels, or mechanized agricultural vehicles or vessels for purposes of diagnosis, repair, or modification of the vehicle or vessel function (codified at 37 CFR 201.40(b)(13)).¹⁰⁶

MEMA, representing manufacturers of replacement vehicle parts, tools, diagnostics, and technologies, states that “completing a repair increasingly requires re-programming or configuring a replacement part so that it can communicate with the vehicle’s electronic systems,” which cannot be accomplished without circumventing a TPM.¹⁰⁷ SEMA, representing businesses that manufacture, distribute, supply, and sell specialty motor vehicle parts, states that the continued yearly technological advancements in vehicles makes the exemption “even more critical for vehicle owners who work on their own vehicles and the service professionals they hire to diagnose, repair, customize, and modify their vehicles.”¹⁰⁸ Both petitioners have participated in prior proceedings concerning this exemption.

The Alliance for Automotive Innovation (“Auto Innovators”) submitted a comment that does not oppose renewal of the exemption but raises concerns with the MEMA and SEMA petitions. Auto Innovators comments that MEMA and SEMA “mischaracterize the scope of the existing exemption and appear to argue for an expanded exemption” that would apply to activities that are prohibited by section 1201’s anti-trafficking provisions.¹⁰⁹ Petitioners’ “suggestions that the existing exemption permits third-party repair shops to circumvent access controls on vehicle software in order to provide commercial repair services are incorrect,” Auto Innovators

asserts, because such activity is “indisputably trafficking in an unlawful service under [s]ections 1201(a)(2) and (b).”¹¹⁰

The Register has addressed the relationship between this exemption and the anti-trafficking provisions, including issues with third-party assistance, in previous rulemaking cycles.¹¹¹ In 2018, the Acting Register declined to express any “view as to whether particular examples of assistance do or do not constitute unlawful circumvention services”—specifically, “whether vehicle or other repair services may run afoul of the anti-trafficking provisions when engaging in circumvention on behalf of customers.”¹¹² The Register reaffirmed this position in subsequent rulemakings.¹¹³ As she observed then, the Librarian’s authority under section 1201(a)(1) to grant exemptions to the anti-circumvention provisions “does not extend to the anti-trafficking provisions.”¹¹⁴ Only Congress may expressly exempt activities that might constitute trafficking.¹¹⁵ Because the legal circumstances have not materially changed since she last considered these issues, and cognizant of the scope of the Librarian’s rulemaking authority, the Register finds no reason to revisit the relationship between third-party assistance and the anti-trafficking provisions. Moreover, reconsidering these issues would fall outside the scope of the streamlined renewal procedure, in which “[o]nly petitions requesting renewal of current exemptions as currently written in the *Code of Federal Regulations*, without modification, may be considered.”¹¹⁶

Based on the information provided in the renewal petitions pertaining to the

¹⁰¹ These exemptions permit circumvention for the purpose of jailbreaking (1) smartphones and other portable all-purpose computing devices, (2) smart televisions, (3) voice assistant devices, and (4) routers and dedicated networking devices. See Electronic Frontier Foundation (“EFF”) Smartphone and Portable All-Purpose Mobile Computing Device Jailbreaking Renewal Pet.; EFF Smart TVs Jailbreaking Renewal Pet.; Software Freedom Conservancy (“SFC”) Smart TVs Jailbreaking Renewal Pet.; EFF Voice Assistant Devices Jailbreaking Renewal Pet.; SFC Routers and Dedicated Network Devices Jailbreaking Renewal Pet.

¹⁰² EFF Smartphone and Portable All-Purpose Mobile Computing Device Jailbreaking Renewal Pet. at 4.

¹⁰³ SFC Smart TVs Jailbreaking Renewal Pet. at 4. The Office notes that SFC filed a highly similar renewal petition in the 2024 rulemaking proceeding. See 2024 SFC Smart TVs Jailbreaking Renewal Pet. If petitioner seeks renewal in future proceedings, the Office suggests that they provide additional information on current consumer interests as stated in the petition. See SFC Smart TVs Jailbreaking Renewal Pet. at 4 (citing to a now defunct SamyGO forum dedicated to “custom Samsung TV firmware”); see also NOI at 34797 n.19.

¹⁰⁴ EFF Voice Assistant Devices Jailbreaking Renewal Pet. at 4.

¹⁰⁵ SFC Routers and Dedicated Network Devices Jailbreaking Renewal Pet. at 4.

¹⁰⁶ MEMA Vehicle or Vessel Repair Renewal Pet.; SEMA Vehicle or Vessel Repair Renewal Pet.

¹⁰⁷ MEMA Vehicle or Vessel Repair Renewal Pet. at 4.

¹⁰⁸ SEMA Vehicle or Vessel Repair Renewal Pet. at 4.

¹⁰⁹ Auto Innovators Vehicle or Vessel Repair Opp. at 1.

¹¹⁰ *Id.* at 2.

¹¹¹ See 2018 Recommendation at 222–25; 2021 Recommendation at 230.

¹¹² 2018 Recommendation at 225.

¹¹³ See 2021 Recommendation at 230 (adhering to the Office’s 2018 position on third-party assistance); 85 FR 65293, 65299–300 (Oct. 15, 2020) (same); cf. 2024 Recommendation at 201–03 (recommending the Librarian adopt an exemption to allow lawful owners or lessees, or those acting on their behalf, to access, store, and share vehicle operational and telematics data while “tak[ing] no position as to whether any particular act of circumvention by third parties on an owner’s or lessee’s behalf would implicate the section 1201(b) prohibition on trafficking”).

¹¹⁴ 2021 Recommendation at 230.

¹¹⁵ To this end, members have introduced legislation that would permit third-party assistance (as well as provision of tools) for particular uses, like farm equipment repair. See FARM Act, H.R. 5857, 119th Cong. (2025); FARM Act, S.3068, 119th Cong. (2025). The Office has expressed support for a statutory change to facilitate the provision of assistance to exemption beneficiaries in appropriate circumstances. See Section 1201 Study at 59–60.

¹¹⁶ 2026 NOI at 34797.

current exemption and the lack of meaningful opposition to its renewal, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

P. Computer Programs—Vehicle or Vessel Operational Data

Multiple organizations petition to renew the exemption for computer programs that control motorized land vehicles, marine vessels, commercial vehicles or vessels, or mechanized agricultural vehicles or vessels for purposes of accessing, storing, and sharing operational data (codified at 37 CFR 201.40(b)(14)).¹¹⁷ ReMA submitted a comment in support of renewal¹¹⁸ and the Auto Innovators submitted a comment opposing renewal.¹¹⁹

Auto Care Association (“ACA”) states that “[n]ew vehicles increasingly rely on access to operational data that may be stored on the vehicle or accessible electronically.”¹²⁰ iFixit explains that exemption beneficiaries need access to vehicles’ operational data for several reasons, including “to understand equipment condition, anticipate service needs, compare performance, and share information with independent repair providers.”¹²¹ Likewise, MEMA states that TPMs “restrict access to electronic control units,” preventing “vehicle owners and lessees from accessing non-copyrightable data that they themselves generate when driving,” leaving drivers unable to “share service alerts, vehicle performance metrics, or driving records with their preferred service provider, aftermarket parts manufacturer, or insurance company.”¹²² SEMA similarly asserts that as vehicles are increasingly integrated with software that “controls the parts and operation of the vehicle,” “[t]elematics data is increasingly important to automotive parts manufacturers, including aftermarket parts suppliers and developers of aftermarket technologies that rely on [this] data to troubleshoot issues, support repairs, validate component performance, develop

predictive maintenance solutions, and offer fleet optimization services.”¹²³

Petitioners participated in the previous rulemaking regarding this exemption or represent or have gathered information from individuals, professionals, or organizations in the vehicle repair industry or that manufacture, distribute, supply, and sell motor vehicle parts.¹²⁴

Auto Innovators does not oppose renewal of the existing exemption, but commented to express concerns that ACA, MEMA, and SEMA misstate the exemption’s scope in their renewal petitions.¹²⁵ Specifically, Auto Innovators object to petitioners’ suggestions that the current exemption extends to “unlawful trafficking in circumvention tools or the unlawful provision of circumvention services by third-party servicers.”¹²⁶ As explained in Section O above, the Office declines to reconsider the relationship between third-party assistance and the anti-trafficking provisions in the context of the streamlined renewal procedure. The same applies to the provision on circumvention tools, which the Office has also previously addressed. In prior rulemakings, the Register declined to exempt the distribution or dissemination of circumvention tools in furtherance of uses found to be noninfringing;¹²⁷ and the law has not materially changed since. In any event, irrespective of how an exemption may be characterized in the renewal petitions or in comments in support or opposition, for purposes of renewal, its scope is defined by the text currently codified in the *Code of Federal Regulations*.

Based on the information provided in the renewal petitions and the lack of meaningful opposition to the current exemption, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

Q. Computer Programs—Repair of Devices Designed Primarily for Use by Consumers

iFixit petitions to renew the exemption for computer programs that control devices designed primarily for

use by consumers for diagnosis, maintenance, or repair of the device (codified at 37 CFR 201.40(b)(15)).¹²⁸ No comments were filed opposing renewal.

iFixit, based on its repair work and information-gathering from device owners and independent technicians, asserts that the need for the exemption continues, as “[s]oftware and access controls remain integral to smartphones, computers, home appliances, game consoles, and other devices.”¹²⁹ For example, iFixit explains that diagnosis and repair of appliances may “require entering a restricted service mode to read fault codes, test components, or clear an error after a physical repair.”¹³⁰

Based on the information provided in the renewal petition and the lack of opposition to renewal, the Office concludes that the conditions that led to adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

R. Computer Programs—Repair of Retail-Level Commercial Food Preparation Equipment

Public Knowledge and iFixit jointly petition to renew the exemption for computer programs that control retail-level commercial food preparation equipment for purposes of diagnosis, maintenance, or repair of the device (codified at 37 CFR 201.40(b)(16)).¹³¹ No comments were filed opposing renewal.

Petitioners, proponents of the exemption in the last proceeding, state that regulatory trends have “spurred growth of ‘smart’ food preparation equipment” and contend that this trend will continue in the coming years.¹³² Petitioners, based on “regular consultation with those impacted by the exemption,” contend that manufacturers can adversely affect device owners and independent repair technicians by preventing them from engaging in repair of commercial food preparation equipment.¹³³

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that

¹²⁸ iFixit Device Repair Renewal Pet. ImageOne Medical Group, LLC (“ImageOne”) submitted a renewal petition, selecting the radio button for the current consumer device repair exemption. See ImageOne Device Repair Renewal Pet. at 3. However, its petition explicitly states that it intended to renew the medical device repair exemption, discussed below. See *id.* at 4; *infra* Section II.S (discussing renewal petitions pertaining to the repair of medical devices and systems).

¹²⁹ iFixit Device Repair Renewal Pet. at 4.

¹³⁰ *Id.*

¹³¹ Public Knowledge & iFixit Retail-Level Commercial Food Preparation Equipment Repair Pet.

¹³² *Id.* at 4.

¹³³ *Id.*

¹¹⁷ Auto Care Association (“ACA”) Vehicle or Vessel Data Renewal Pet.; iFixit Vehicle or Vessel Data Renewal Pet.; MEMA Vehicle or Vessel Data Renewal Pet.; SEMA Vehicle or Vessel Data Renewal Pet.

¹¹⁸ ReMA Vehicle or Vessel Data Supp.

¹¹⁹ Auto Innovators Vehicle or Vessel Data Opp.

¹²⁰ ACA Vehicle or Vessel Data Renewal Pet. at 4.

¹²¹ iFixit Vehicle or Vessel Data Renewal Pet. at 4.

¹²² MEMA Vehicle or Vessel Data Renewal Pet. at 4.

¹²³ SEMA Vehicle or Vessel Data Renewal Pet. at 4.

¹²⁴ MEMA Vehicle or Vessel Data Renewal Pet. at 4; SEMA Vehicle or Vessel Data Renewal Pet. at 4.

¹²⁵ Auto Innovators Vehicle or Vessel Data Opp. at 1–3.

¹²⁶ *Id.* at 2–3.

¹²⁷ See, e.g., 2024 Recommendation at 154; 2021 Recommendation at 230; 2018 Recommendation at 225–26.

the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

S. Repair of Medical Devices and Systems

The Office received multiple petitions to renew the exemption to access computer programs that are contained in and control the functioning of medical devices or systems, and related data files, for diagnosis, maintenance, or repair (codified at 37 CFR 201.40(b)(17)).¹³⁴ One comment was filed in support of the renewal petitions;¹³⁵ four comments were filed in opposition.¹³⁶

Seven of the eight petitions assert a continuing need and justification for the exemption.¹³⁷ For example, BMI,

Caylor, and ECMS assert that the exemption is both “critical” and essential to timely diagnosing and completing the necessary maintenance and repairs of medical devices.¹³⁸ ECMS explains that “[a]ccess to software functions, diagnostic information, system logs, error logs, and other related data files is often necessary to identify the cause of equipment failures and to perform appropriate maintenance and repairs.”¹³⁹ iFixit asserts that “[l]awfully acquired medical devices and systems remain dependent on embedded software, diagnostic programs, calibration functions, configuration data, and related data files” that must be accessed to complete the required diagnosis maintenance and repair.¹⁴⁰ ImageOne states that “[p]assword-protected diagnostic software and restricted access to error logs and service data files routinely interfere with timely diagnosis and repair,” noting certain types of repairs “require direct access to software-generated error logs to accurately isolate the failure and complete repair without unnecessary downtime.”¹⁴¹ According to Marshall Shannon, “[m]odern medical devices cannot be safely installed or serviced without interacting with embedded software, service modes, configuration files, logs, certificates, credentials, and diagnostic utilities.”¹⁴² Trimedx reports that it relies on the current exemption to repair medical systems and describes a recent incident where TPMs “prevented access to [the] necessary software keys required” to repair a device, which left it “to choose between accepting [manufacturer]-only servicing at inflated costs or leaving the device inoperable”; resolution only occurred after “extended negotiations” between Trimedx and the

manufacturer.¹⁴³ Petitioners have personal knowledge of and experience with this exemption; each either repairs, maintains, services, or sells medical systems and devices, or represents or consults with entities or individuals that repair, maintain, service, or sell medical systems and devices.

AMT Imaging Solutions, an independent service organization that services medical equipment, concurs with petitioners that the need for the exemption continues. It comments that “[w]ithout the ability to lawfully access [embedded medical device software] programs and files for diagnosis, maintenance, and repair, hospitals and imaging centers lose a competitive service option, and patients face longer downtime when equipment fails.”¹⁴⁴ In addition, AMT Imaging Solutions cites the D.C. Circuit’s recent decision in *Medical Imaging & Technology Alliance v. Library of Congress* (“MITA”) as “confirm[ation] that the exemption was lawfully adopted.”¹⁴⁵

Comments opposing renewal of the medical device repair exemption assert that, contrary to petitioners’ statements, the rulemaking record from prior proceedings no longer serves as a valid or reliable basis for readopting the current exemption.¹⁴⁶ AdvaMed and Philips present legal and factual developments as evidence supporting “meaningful opposition” to renewal.

AdvaMed and Philips both cite the recent D.C. Circuit opinion in *MITA* as a new legal development affecting the scope of the current exemption and the fair use analysis.¹⁴⁷ Although the court affirmed dismissal of their challenge to the exemption, AdvaMed notes that the D.C. Circuit, like the Library of Congress and the Office, declined to address any alleged distinction between “repair software” and “clinical-operation software” because “[a]ppellants did not demonstrate before the agency the existence of this distinction that it now presses.”¹⁴⁸ The court observed that, based on its review of the administrative record, opponents of the exemption addressed this “possible distinction only in vague terms and provide[d] no

¹³⁴ See Brown’s Medical Imaging (“BMI”) Medical Device Repair Renewal Pet.; Caylor Equipment Services (“Caylor”) Medical Device Repair Renewal Pet.; Crothall Facilities Management, Inc. (“Crothall”) Medical Device Repair Renewal Pet.; East Coast Medical Systems (“ECMS”) Medical Device Repair Renewal Pet.; iFixit Medical Device Repair Renewal Pet.; ImageOne Medical Device Repair Renewal Pet. (On its renewal petition, ImageOne selected the radio button for the current consumer device repair exemption; this selection appears to be in error as the narrative portion of the petition explicitly refers to the medical device repair exemption. Accordingly, the Office treats ImageOne’s petition as a renewal of the medical device repair exemption.); Shannon Medical Device Repair Renewal Pet.; Trimedx Holdings, LLC (“Trimedx”) Medical Device Repair Renewal Pet. Marshall Shannon, after experiencing technical issues with submitting the petition forms provided by the Office, timely submitted a “Petition to Renew and Supporting Statement and Petition for a New or Modified Exemption for Medical-Device Diagnosis, Installation, Maintenance, Repair, Calibration, and Return to Service.” To the extent that Shannon’s submission seeks to renew the existing exemption as currently written in the *Code of Federal Regulations*, without modification, the Office considers it as a renewal petition. See NOI at 34797. The Office will consider portions of Shannon’s submission that seek “clarification or a modified exemption” as a petition for an expanded exemption. In addition, Trimedx lists “regulatory compliance” among the purposes covered by the existing exemption. Trimedx Medical Device Repair Renewal Pet. at 4. Because that use is not expressly covered by the exemption, however, the Office will not evaluate it under the renewal procedure and instead will consider it as a proposed expansion. See *infra* Section III.H (discussing Proposed Class 8: Computer Programs—Repair).

¹³⁵ AMT Imaging Solutions LLC Medical Device Repair Supp.

¹³⁶ AdvaMed Medical Device Repair Opp. #1; Joint Creators Medical Device Repair Opp.; Philips Medical Device Repair Opp. AdvaMed submitted an additional comment opposing the proposed expansion of the medical device repair exemption in Shannon’s medical device repair petition. See AdvaMed Medical Device Repair Opp. #2.

¹³⁷ An eighth petition, submitted by Crothall, did not meet the Office’s requirements for renewal petitions. While the Office requires “a brief explanation summarizing the basis for claiming a continuing need and justification for the exemption,” NOI at 34797, Crothall’s petition,

which is substantively identical to its renewal petition submitted in the last cycle, see 2024 Crothall Medical Device Repair Renewal Pet., contains only two brief sentences stating that its ability to service medical devices “can be impacted” by software restrictions. See Crothall Medical Device Repair Renewal Pet. at 4 (“[Crothall’s] ability to service a device without using the installed software and data files can be impacted by software access. Access to software error logs is a critical function in the optimal diagnosis, maintenance, and repair of devices.”). Similarly to the last cycle, because other petitioners provide the required information for renewal to be considered, Crothall’s petition is not discussed further.

¹³⁸ BMI Medical Device Repair Renewal Pet. at 4; Caylor Medical Device Repair Renewal Pet. at 4; ECMS Medical Device Repair Renewal Pet. at 4.

¹³⁹ ECMS Medical Device Repair Renewal Pet. at 4.

¹⁴⁰ iFixit Medical Device Repair Renewal at 4.

¹⁴¹ ImageOne Medical Device Repair Renewal at 4.

¹⁴² Shannon Medical Device Repair Renewal at 3.

¹⁴³ Trimedx Medical Device Repair Renewal Pet. at 4.

¹⁴⁴ AMT Imaging Solutions Medical Device Repair Supp.

¹⁴⁵ *Id.* (citing *Med. Imaging and Tech. All. v. Libr. of Cong.* (“MITA”), No. 25–5328, slip op. at 12 (D.C. Cir. Sep. 1, 2026)).

¹⁴⁶ AdvaMed Medical Device Repair Opp. #1 at 2–4; Philips Medical Device Repair Opp. at 1–2.

¹⁴⁷ AdvaMed Medical Device Repair Opp. #1 at 3, 5–7; Philips Medical Device Repair Opp. at 5.

¹⁴⁸ AdvaMed Medical Device Repair Opp. #1 at 3 (citing *MITA*, slip op. at 13–15).

supporting evidence.”¹⁴⁹ Philips also stresses this distinction and claims that *MITA* “established the disputed scope of the exemption” as covering “clinical operational software” but not “separately protected service software.”¹⁵⁰ Philips further contends that arguments made in the case “highlighted the night-and-day difference between the fair use analysis for clinical operational software on the one hand and service software on the other.”¹⁵¹

These commenters also offer factual evidence that was not presented in prior rulemakings to argue that the administrative record, for purposes of streamlined renewal, is no longer sufficient. AdvaMed’s submission includes “first-hand evidence from medical device manufacturers” in the form of sworn declarations from executives with “expert knowledge and operational responsibility for the servicing of their company’s medical devices.”¹⁵² These declarations, AdvaMed asserts, establish three facts absent from the administrative record from prior rulemakings. Specifically, they allege: (1) there are three categories of copyrighted works at issue and that “System Servicing/Diagnostic Software” and “Maintenance-Related Documentation” are works distinct from “Clinical Operation Software”; (2) different TPMs protect these categories of works; and (3) manufacturers license and commercially exploit servicing materials separately from the sale or lease of a medical device.¹⁵³ Philips, in describing its own products, similarly states that there are distinct types of medical device software that are protected by different TPMs.¹⁵⁴

In addition to providing evidence to challenge the basis for re-adopting the current exemption, AdvaMed and Philips assert that the petitions fall short of the standard for renewal. AdvaMed details specific deficiencies with each petition, both procedural (e.g., missing a legible name or signature, wrong exemption selected on petition form) and substantive (e.g., failure to show personal knowledge or experience of adverse effects).¹⁵⁵ Philips faults all of

the petitions for “describing a need for service works as opposed to clinical operational software” because they “seek to renew an exemption that was never intended to cover the precise works they wish to access.”¹⁵⁶

Finally, all four comments opposing renewal object to the consideration of proposals that would expand the current exemption under the streamlined renewal procedure. As noted above, Shannon seeks “clarification or a modified exemption” and Trimedx’s petition includes “regulatory compliance of [medical] devices” among the proposed uses. Opponents state that, to the extent that these petitions propose activity that exceeds the scope of the current exemption, it is inappropriate for the Office to evaluate such uses without affording affected persons the opportunity to provide notice and comment.¹⁵⁷

The Office may recommend renewal of a current exemption under the streamlined process where it determines that a petitioner has made a minimal showing that the record supporting the exemption remains representative of current legal and factual circumstances. This minimal showing, however, can be overcome by “meaningful opposition.”¹⁵⁸ Meaningful opposition may be established with “evidence that the prior rulemaking record is no longer a valid basis to support recommending renewal of an exemption.”¹⁵⁹ Specifically, evidence should consist of new legal or factual developments that address “the reliability of the previously[] analyzed administrative record.”¹⁶⁰

The Office has reviewed participants’ submissions and finds that the new evidence and arguments provided in the opposition comments collectively amount to meaningful opposition. While petitioners provided evidence that diagnosis, maintenance, and repair of medical devices and systems continue to be adversely affected by the prohibition against circumvention, the opposition comments include new evidence and arguments that may cast uncertainty on the current reliability of the existing administrative record. They provide evidence of different types of medical device software that are configured differently depending on the

purpose of the software and, in some cases, may not be stored on the device. That evidence raises questions about whether the scope of the current exemption, which permits circumvention to access “[c]omputer programs that are contained in and control the functioning of” those devices, is defined with sufficient specificity.¹⁶¹

Further, opponents’ new evidence bears on the fact-specific fair use analysis and the statutory factors for adverse effects determinations. Although opponents cite the *MITA* decision as a “new legal development,” the D.C. Circuit’s opinion, like the Supreme Court’s decision in *Andy Warhol Found. for the Visual Arts v. Goldsmith* (“*Warhol*”), did not change the legal framework for analyzing the proposed uses.¹⁶² Indeed, after considering the legal analysis in prior rulemakings, the court concluded that “the Librarian’s adoption of the medical device repair exemption was lawful, reasonable, and supported by ‘thorough and well-reasoned explanations from the Eighth and Ninth Triennial Rulemaking procedures.’”¹⁶³ Nevertheless, the opinion highlighted a disputed *factual* issue that could affect the section 1201 analysis, *i.e.*, opponents’ contention “that there is a distinct body of repair software independent from the clinical-operation software and that it occupies its own standalone market.”¹⁶⁴ While the court rightly rejected this assertion because appellants “made no such record in the rulemaking process or before the district court,”¹⁶⁵ opponents have appropriately raised it here. The comments outlining these factual developments and their legal significance therefore constitute meaningful opposition.¹⁶⁶

¹⁶¹ 37 CFR 201.40(b)(17).

¹⁶² See 2024 Recommendation at 38 (rejecting arguments that *Warhol* amounted to an intervening change in the law that undermined the validity of the medical device repair exemption).

¹⁶³ *MITA*, slip op. at 12.

¹⁶⁴ *Id.* at 13.

¹⁶⁵ *Id.*

¹⁶⁶ Because the Office has determined that medical device repair is ineligible for the streamlined renewal procedure and will instead evaluate the exemption after seeking notice and comment, the Office need not determine whether any renewal petitions would inappropriately expand the exemption. NOI at 34797–98; see also 88 FR at 37487 (explaining that when current exemptions are not recommended for renewal, the petition “automatically convert[s] into a petition for a new exemption,” that proceeds through three rounds of public comment). All medical device repair petitions and comments, pertaining to both the existing exemption and proposed expansions, will be considered together as part of a single proposed class.

¹⁴⁹ *Id.* (citing *MITA*, slip op. at 15).

¹⁵⁰ Philips Medical Device Repair Opp. at 1.

¹⁵¹ *Id.*; see AdvaMed Medical Device Repair Opp. #1 at 5–7 (commenting that the *MITA* court analyzed fair use only with respect to “Clinical Operating Software” and that this analysis is different for “Servicing Works”).

¹⁵² AdvaMed Medical Device Repair Opp. #1 at 3–5, 7–17, Exs. A–E.

¹⁵³ *Id.*

¹⁵⁴ Philips Medical Device Repair Opp. at 3, Ex. A (Jacqueline Dickson Decl.).

¹⁵⁵ AdvaMed Medical Device Repair Opp. #1 at 20–24.

¹⁵⁶ Philips Medical Device Repair Opp. at 6–7.

¹⁵⁷ AdvaMed Medical Device Repair Opp. #1 at 24–28; AdvaMed Medical Device Repair Opp. #2; Joint Creators Medical Device Repair Opp. at 2; Philips Medical Device Repair Opp. at 7–8.

¹⁵⁸ NOI at 34797.

¹⁵⁹ *Id.* (quoting 88 FR 37486, 37488 (June 8, 2023)).

¹⁶⁰ *Id.* at 34797–98 (quoting 85 FR at 65295).

In light of this finding, to fully consider whether the basis for the current medical device repair exemption remains sound, as well as whether it should be modified or expanded, the Office will evaluate all the proposed repair-related uses of copyrighted works on medical devices and systems together as a potential new exemption in the public comment phase.¹⁶⁷ This process will allow participants to develop a new administrative record for medical device repair by submitting comments and participating in a public hearing.¹⁶⁸ It will also promote administrative efficiency in considering the scope of the proposed exemption as both opponents and some petitioners seek clarification about its breadth. The Office has therefore included the current exemption in its analysis and classification of proposed new or expanded exemptions as Proposed Class 8: Computer Programs—Repair, below.¹⁶⁹

T. Computer Programs—Security Research

Multiple organizations and security researchers petition to renew the exemption permitting circumvention for purposes of good-faith security research (codified at 37 CFR 201.40(b)(18)).¹⁷⁰ No comments were filed opposing renewal.

Professor Michael Specter states that security researchers “play a vital role” in cybersecurity, as “vulnerability disclosure and remediation are key to securing existing infrastructure.”¹⁷¹ Professors Matt Blaze and Steven Bellovin assert that an exemption is necessary not only because they have personal knowledge of security researchers who rely on the exemption but that “during the last three years, one of us has continued to be impacted by threats of prospective litigation from copyright holders in connection with his security research on software in

voting systems.”¹⁷² Additionally, MEMA explains that the exemption is needed because it enables its members and other beneficiaries “to develop and test aftermarket parts, diagnostic tools, and service equipment with full knowledge of potential security implications” that may otherwise go undetected, putting vehicle owners and the public at risk.¹⁷³ SFC states that the exemption continues to be used by “privacy and security researchers who investigate and publish information about privacy [] flaws in computing devices” and “individual consumers and hobbyists who wish to prevent their private data from being disclosed by the devices they own.”¹⁷⁴

Based on the information provided in the renewal petitions and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

U. Computer Programs—Video Game Preservation

LCA, Dan Elkins, and Ken Austin petition to renew the exemption for individual play by gamers and preservation of video games by a library, archives, or museum for which outside server support has been discontinued, and preservation by a library, archives, or museum of discontinued video games that never required server support (codified at 37 CFR 201.40(b)(19)).¹⁷⁵ No comments were filed opposing renewal.

According to the LCA petition, the exemption “has had continuing utility for video game preservation by libraries, archives, and museums” and will continue to be needed in the future because “[s]ubstantial numbers of historic video games were published with [TPMs] in place, and digital preservation is an ongoing, iterative process.”¹⁷⁶ LCA asserts the exemption has become a “crucial tool” in these institutions’ “ongoing efforts to save digital game culture before it disappears.”¹⁷⁷ LCA petitioned for this exemption during the 2018 triennial rulemaking and has petitioned for its renewal in each subsequent rulemaking.¹⁷⁸ Elkins states that owners

of lawfully acquired videogames, like himself, “remain exposed to the continuing risk that authentication or server dependencies can prevent access to [the] functionality of software they lawfully acquired,” such as when a videogame developer stopped supporting an original version of a game for online use that he purchased.¹⁷⁹ Austin also attests that he has games “with [digital rights management (“DRM”)] that can no longer authenticate due to defunct online servers” and without the exemption, he cannot access the games to restore playability, “despite the fact [he] lawfully acquired them.”¹⁸⁰ These two individual petitioners possess personal knowledge and experience relevant to the exemption’s provisions.

Based on the information provided in the renewal petitions and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

V. Computer Programs—Software Preservation

LCA petitions to renew the exemption for computer programs, other than video games, for the preservation of computer programs and computer program-dependent materials by libraries, archives, and museums (codified at 37 CFR 201.40(b)(20)).¹⁸¹ No comments were filed opposing renewal.

LCA states that libraries, archives, and museums continue to need and rely on the exemption to preserve and curate software and materials dependent on software, which is “an ongoing [and] iterative process.”¹⁸² For example, it explains that “[s]ubstantial numbers of computer programs were published with [TPMs] in place,” and that “[r]esearch interest in preserved software will only grow as scholars and students become increasingly aware of the research value of these materials.”¹⁸³ On behalf of its members who rely on this exemption, LCA has participated in previous triennial rulemaking proceedings, petitioning for the adoption and renewal of this exemption.¹⁸⁴

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that

¹⁶⁷ NOI at 34797.

¹⁶⁸ See *AdvaMed Medical Device Repair Opp. #1* at 3 (proposing that the Office deny streamlined renewal of the exemption as written and instead “carry the question forward into the public comment phase where a record can be built”); *Philips Medical Device Repair Opp. #2*, 8 (“[T]he Copyright Office should decline to renew the exemption under the streamlined procedure and require proponents to develop a disaggregated record in a full rulemaking that provides particularized fair use analysis for each distinct category of copyrighted work residing on medical devices.”).

¹⁶⁹ See *infra* Section III.H (discussing Proposed Class 8: Computer Programs—Repair).

¹⁷⁰ *Blaze & Bellovin Security Research Renewal Pet.*; *MEMA Security Research Renewal Pet.*; *Specter Security Research Renewal Pet.*; *SFC Security Research Renewal Pet.*

¹⁷¹ *Specter Security Research Renewal Pet.* at 4.

¹⁷² *Blaze & Bellovin Security Research Renewal Pet.* at 4.

¹⁷³ *MEMA Security Research Renewal Pet.* at 4.

¹⁷⁴ *SFC Security Research Renewal Pet.* at 4.

¹⁷⁵ *LCA Abandoned Video Games Renewal Pet.*; *Elkins Abandoned Video Games Renewal Pet.*; *Austin Abandoned Video Games Renewal Pet.*

¹⁷⁶ *LCA Abandoned Video Games Renewal Pet.* at 4.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Elkins Abandoned Video Games Renewal Pet.* at 4.

¹⁸⁰ *Austin Abandoned Video Games Renewal Pet.* at 4.

¹⁸¹ *LCA Software Preservation Renewal Pet.*

¹⁸² *Id.* at 4.

¹⁸³ *Id.*

¹⁸⁴ *Id.*

the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

W. Computer Programs—3D Printing

Michael Weinberg petitions to renew the exemption for computer programs that operate 3D printers to allow use of alternative material (codified at 37 CFR 201.40(b)(21)).¹⁸⁵ No comments were filed opposing renewal.

Weinberg, who has participated in each triennial rulemaking in which this exemption has been considered, declares that he has been “involved with the 3D printing community and industry for over a decade.”¹⁸⁶ The petition asserts that while 3D printer manufacturers “continue to use TPMs to limit the types of materials used in printers,” the current exemption has continued to result in “an expansion of third-party materials available for 3D printers.”¹⁸⁷

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

X. Computer Programs—Copyright License Investigation

SFC petitions to renew the exemption for computer programs, for the purpose of investigating potential infringement of free and open source computer programs (codified at 37 CFR 201.40(b)(22)).¹⁸⁸ No comments were filed opposing renewal.

SFC states it “regularly and routinely investigates computers and computerized devices . . . to determine whether the manufacturers are complying with the relevant [free and open source software] licenses.”¹⁸⁹ It also states that “reports of violations of [these] licenses have more than doubled in only the last year” and that it has recently observed “an increase in locking down computerized devices” that prevents investigations into license compliance.¹⁹⁰ SFC has participated in the previous rulemakings regarding this exemption and contributed to the rulemaking record that led to the

Register recommending the exemption.¹⁹¹

Based on the information provided in the renewal petition and the lack of opposition, the Office concludes that the conditions that led to the adoption of this exemption are likely to continue during the next triennial period. Accordingly, the Register intends to recommend renewal.

III. Analysis and Classification of Proposed New or Expanded Exemptions

In addition to petitions to renew existing exemptions, the Office received twenty-five petitions for new or expanded exemptions. The Office has reviewed and consolidated related and/or overlapping proposed exemptions to simplify the rulemaking process and encourages joint participation among parties with common interests (although collaboration is not required).¹⁹² The Office proposes ten consolidated classes of works, including the meaningfully opposed renewal petition.

Each proposed class is briefly described below, and additional information can be found in the underlying petitions posted on the Office’s website. As explained in the NOI, the proposed classes represent “‘only a starting point for further consideration in the rulemaking proceeding,’ and will be subject to ‘further refinement based on the record.’”¹⁹³ The description of each class also includes preliminary legal and factual areas of interest that the Office hopes commenters will address in their submissions. These early observations are offered without prejudice to the Office’s ability to raise other questions or concerns at later stages of the proceeding, and commenters should offer all legal arguments and evidence they believe necessary to create a complete record. Finally, the Office reminds exemption proponents that “where an exemption request resurrects legal or factual arguments that have been previously rejected, the Office will continue to rely on past reasoning to dismiss such arguments in the absence of new information.”¹⁹⁴

A. Proposed Class 1: Audiovisual Works—Accessibility and Captioning

Accessibility Petitioners jointly petition for a new exemption to permit libraries and other public entities to circumvent access controls on

audiovisual works hosted on web or mobile app interfaces for purposes of captioning and audio description “to provide the accessibility required by recently adopted regulations relating to the Americans with Disabilities Act.”¹⁹⁵ They assert that an exemption is needed for public entities to comply with recently adopted accessibility regulations that “ensure accessibility features, such as audio descriptions or synchronized captions, are available to persons with disabilities.”¹⁹⁶

The current captioning and audio description exemption is limited to disability services offices or similar units at educational institutions.¹⁹⁷ Accessibility Petitioners seek an exemption for a broader class of public entities to correspond with the entities subject to 28 CFR 35.200, including public libraries that will be obligated to provide accessible versions of online content they supply to their users.¹⁹⁸

The Office seeks comment on whether the proposed exemption should be adopted, including any proposed regulatory language. Commenters should describe with specificity the relevant TPMs sought to be circumvented and whether their presence is adversely affecting noninfringing uses. Commenters should address whether the works are available in accessible formats that do not require circumvention and any anticipated effect that circumvention of TPMs would have on the potential market for or value of the relevant copyrighted works.

B. Proposed Class 2: Audiovisual Works—Criticism and Comment

Jayden Milne petitions to expand the current exemption allowing for circumvention of access controls protecting motion pictures on DVDs, Blu-ray discs, and digitally transmitted video for criticism and comment purposes.¹⁹⁹ Milne requests that the exemption be extended to include Ultra HD Blu-ray Discs protected by Advanced Access Content System 2 (“AACS2”) and not be limited to non-commercial uses, with the provision

¹⁹⁵ Accessibility Petitioners Class 1 Pet. at 2.

¹⁹⁶ *Id.*; see also 28 CFR 35.200 (discussing the requirements for web and mobile accessibility as part of the Americans with Disabilities Act (“ADA”)).

¹⁹⁷ Accessibility Petitioners Class 1 Pet. at 2; see 37 CFR 201.40(b)(2).

¹⁹⁸ Accessibility Petitioners Class 1 Pet. at 2 (noting that “[t]he broad definition of public entity under the Americans with Disabilities Act includes ‘any state or local government, any department, agency, special purpose district, or other instrumentality of a state or local government’”).

¹⁹⁹ Milne Class 2 Pet. at 2.

¹⁸⁵ Weinberg 3D Printers Renewal Pet.

¹⁸⁶ *Id.* at 4.

¹⁸⁷ *Id.*

¹⁸⁸ SFC Copyright License Investigation Renewal Pet.

¹⁸⁹ *Id.* at 4.

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² NOI at 34798.

¹⁹³ *Id.* (quoting 88 FR at 37489).

¹⁹⁴ Section 1201 Study at 147; see also 79 FR 55687, 55690 (Sep. 17, 2014).

that certain videos would be licensed, sold, or distributed for commercial purposes.²⁰⁰ The proposed expansion also appears to eliminate the current use categories of criticism and comment so that users, who are “[i]ndividuals who own the disc, remain in continuous lawful possession, and create the critical work alone, with collaborators, or for an entity” can incorporate the work “into a video, film, or nonfiction multimedia e-book for criticism or comment.”²⁰¹ Milne explains that an exemption is needed because “some UHD editions contain distinct cuts, restorations, or presentation attributes, while licensed Windows-PC UHD-disc playback has ceased, narrowing potential source workflows.”²⁰²

The Office notes that in the two previous triennial rulemakings it considered whether this exemption should be expanded to include AACS2 technology. During those rulemakings, the Office determined that the rulemaking records were insufficient to justify proposed expansions.²⁰³ The Office seeks comment on whether any changed legal or factual developments warrant altering those determinations and whether, or to what extent, the proposed expansion should be adopted, including any proposed regulatory language. Commenters should also address whether it is necessary to expand the exemption beyond the uses permitted under the current exemption (*i.e.*, documentary filmmaking, noncommercial videos, and nonfiction multimedia e-books), to cover all criticism and commentary, including commercial uses, and the extent to which those other uses are or are likely to be adversely affected. Commenters should also discuss whether eligible users may access the works in ways not requiring circumvention.

C. Proposed Class 3: Audiovisual Works—Playback on Unsupported Devices

Jayden Milne submits two petitions seeking new exemptions for contemporaneous, private, local, noncommercial playback of DVD, Blu-ray, and Ultra HD Blu-ray discs on an

owner-controlled general-purpose personal computer for which no licensed player is available.²⁰⁴ The proposed exemptions would permit circumvention of discs protected by Content Scramble System (“CSS”), Advanced Access Content System (“AACS”), AACS2, and BD+.²⁰⁵

The Office notes that the Register recommended against similar proposals in the 2015, 2010, 2006, 2003, and 2000 triennial rulemakings.²⁰⁶ These proposed exemptions would have permitted the circumvention of DVD access controls to enable playback on personal computers running incompatible operating systems, such as Linux. For instance, in the 2003 rulemaking, the Office explained, “[w]hile it is unfortunate that persons wishing to play CSS-protected DVDs on computers with the Linux operating system have few options,” they have the “same options that other consumers have. . . . [A]ll motion pictures on CSS-protected DVDs remain available even to Linux users. The Linux users simply must use the consumer electronic devices used by most consumers to view those DVDs.”²⁰⁷ Therefore, the Office seeks comment on any differences in the two proposals and whether any changed legal or factual circumstances warrant a different conclusion here. Additionally, the Office seeks general comment on the impact this proposed exemption would have on the ability of rightsholders to exercise their rights and the ability of consumers to make noninfringing uses of audiovisual works. Commenters addressing both proposals should provide supporting evidence sufficient with respect to each, including evidence establishing adverse effects on noninfringing uses with respect to each proposal and similarities between the proposals, if any, regarding the relevant factual and legal issues.

²⁰⁴ See Milne Class 3 Pet. #1 at 2 (Unsupported-Platform Optical-Disc Playback); Milne Class 3 Pet. #2 at 2 (Ultra HD Blu-ray PC Playback).

²⁰⁵ Milne Class 3 Pet. #1 at 2; Milne Class 3 Pet. #2 at 2.

²⁰⁶ See 2015 Recommendation 126; U.S. Copyright Office, Section 1201 Rulemaking: Fourth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 224 (2010) (“2010 Recommendation”), <https://cdn.loc.gov/copyright/1201/2010/initialed-registers-recommendation-june-11-2010.pdf>; U.S. Copyright Office, Section 1201 Rulemaking: Third Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention, Recommendation of the Register of Copyrights 72–73 (2006) (“2006 Recommendation”), https://cdn.loc.gov/copyright/1201/docs/1201_recommendation.pdf; 2003 Recommendation at 145–46; 65 FR 64556, 64569 (Oct. 27, 2000).

²⁰⁷ 2003 Recommendation at 145–46.

D. Proposed Class 4: Audiovisual Works—Replacement

Six petitions seek to circumvent access controls on motion pictures distributed on optical discs or through streaming services to make replacement copies when the disc or the equipment needed to play it are unavailable, or a digital copy of the work is no longer usable or available. For reasons of administrative efficiency, the Office has grouped these proposals into one overall class with three subclasses. Each commenter may submit only a single comment addressing Class 4, which may address some or all subclasses. Supporting evidence must be sufficient to establish an adverse effect on noninfringing uses with respect to each subclass.

Proposed Subclass 4(a): Preservation

Three separate petitions, two from Jayden Milne and one from James and Rebekkah Stakebake, propose a new exemption to facilitate personal, noncommercial preservation of audiovisual works stored on lawfully acquired DVDs, Blu-ray discs, and Ultra HD Blu-ray discs protected by CCS, AACS, AACS2, and BD+.²⁰⁸

One Milne petition and the Stakebakes’ petition both propose an exemption that would permit individuals to create digital copies due to disc damage or deterioration.²⁰⁹ Milne further specifies that the original disc would be “retained and retired from ordinary viewing once the replacement is used” and could be voluntarily transferred, but the proposal would still permit certain subsequent uses of both the original and replacement disc.²¹⁰ In a second petition, Milne proposes an exemption that would permit individuals to preemptively preserve discs prior to deterioration by creating one noncommercial copy, which could be used for “integrity testing and private viewing.”²¹¹ The petition does not

²⁰⁸ Milne Class 4(a) Pet. #1 at 2 (Preventative Personal Preservation); Milne Class 4(a) Pet. #2 at 2 (Damaged or Deteriorating Optical-Disc Replacement); Stakebake & Stakebake Class 4(a) Pet. at 2.

²⁰⁹ See Stakebake & Stakebake Class 4(a) Pet. at 2 (identifying purpose of “[p]ersonal, noncommercial archival preservation and creation of backup copies to prevent loss due to physical media deterioration [and] damage”); Milne Class 4(a) Pet. #2 at 2 (“The purpose is to make one secured, noncommercial personal replacement while an owned disc is actually damaged or objectively deteriorating but remains recoverable.”).

²¹⁰ Milne Class 4(a) Pet. #2 at 2.

²¹¹ Milne Class 4(a) Pet. #1 at 2. Petitioner proposes “owner-only use” as a fallback if household viewing is not included in the exemption.

²⁰⁰ *Id.*

²⁰¹ *Id.*; see 37 U.S.C. 201.40(b)(1)(i).

²⁰² Milne Class 2 Pet. at 2.

²⁰³ See 2021 Recommendation at 39–40 (“[T]he record does not support a finding that AACS2 technology is adversely affecting noninfringing uses or that it is sufficiently similar to AACS1 to be covered by the current exemption.”); 2018 Recommendation at 39–41 (“None of the petitions expressly seek expansion to AACS2, and the record does not support a finding that such technology is adversely affecting noninfringing uses or that it is sufficiently similar to AACS1 to be covered by the current exemption.”).

specify whether the copy would be on disc or digital.

The Office notes that the Register considered a similar request in the 2021 rulemaking pertaining to preservation and replacement copies of motion pictures by libraries, archives, and museums.²¹² In that rulemaking, the Register recommended the exemption be granted in part and denied in part. With respect to damaged or deteriorating discs, the Register recommended an exemption, provided that the motion pictures in question were not reasonably available for purchase or streaming, but determined that proponents had not established that copying discs prior to deterioration was fair use.²¹³ The Librarian adopted this exemption in the final rule and renewed it in the 2024 rulemaking;²¹⁴ the Register is again recommending it for renewal in this rulemaking.²¹⁵

The Office seeks comment on whether preservation for personal purposes, as opposed to institutional purposes, impacts the analysis and whether there have been any legal or factual developments regarding preemptive preservation. The Office encourages commenters to develop the legal and factual administrative record, including addressing with specificity the format of the proposed copies, the proposed uses of both the original and the copy, and the impact the exemption would have on the market for the copyrighted works at issue.

Proposed Subclass 4(b): Hardware Obsolescence

Two petitions propose a new exemption that would allow circumvention of technical measures protecting motion pictures and television programs that are stored and released on optical discs.²¹⁶ James and Rebekkah Stakebake, in the same petition as discussed in class 4(a), also petition to allow “[p]ersonal, noncommercial archival preservation and creation of backup copies to prevent loss due to . . . hardware obsolescence,” where the media is lawfully purchased.²¹⁷ The Stakebakes explain that the TPMs on the physical media “currently prevent users from copying the content to secure digital storage for preservation purposes.”²¹⁸

Jamark also petitions for an exemption permitting both “individual consumers and physical media rental libraries maintaining circulating collections” to “format-shift[] . . . a lawfully owned disc to a digital file for personal or controlled-circulation use,” when hardware required to play that disc is “experiencing continuing, accelerating decline in availability.”²¹⁹ It asserts that “[w]hile used playback hardware for some formats remains findable on secondary markets, that supply is finite, non-replenishing, and subject to ongoing depletion through failure and attrition.”²²⁰ While Jamark seeks to allow personal and commercial users to make use of the backup copy in circumstances where the work is otherwise unavailable, the Stakebakes’ petition does not specify conditions for use of the copy.²²¹

The Office seeks comment on whether this proposed exemption should be adopted, including any proposed regulatory language. The Office notes that the Register has repeatedly declined to recommend proposed exemptions for space- or format-shifting, finding that proponents failed to establish that format-shifting is a noninfringing use.²²² The Office seeks comment on all aspects of this proposed exemption, including whether, in the past three years, there has been a change in the legal or factual circumstances regarding whether space-shifting and format-shifting are noninfringing fair uses and the effects the proposed exemption would have on the market for or value of the relevant works.

Proposed Subclass 4(c): Digital Service Discontinuation

Two petitions filed by Jayden Milne and Zakaria Zerhouane propose a new exemption to circumvent technological protection measures that control access to audiovisual works where licensed or lawful access to a digital version of the work is discontinued.²²³ The petitions seek to allow circumvention of TPMs on physical media, such as those protected by CSS and AACS, as well as “proprietary [digital rights management], geo-locking, and session-based access controls” on streaming

platforms.²²⁴ Petitioners explain that many distributors who previously made these works accessible are now “defunct,” distributors’ websites and services “ended,” and “previously available . . . digital copies . . . no longer supported or available.”²²⁵ For physical media, such as lawfully made and acquired DVDs, expired codes attached to that media “are not renewed or replaced” or distributors “have since dissolved, entered bankruptcy, or ceased operations.”²²⁶ The petitions limit circumvention to individual owners, “individual viewers, researchers, archivists, and preservationists,” for personal and noncommercial uses, including preservation.²²⁷

The Office seeks comment on whether the proposed exemption should be adopted, including any proposed regulatory language. Commenters are encouraged to develop the legal and factual administrative record in their initial submissions, including describing with specificity the relevant TPMs for all proposed media and platforms containing access controls they seek to circumvent and whether the presence of the TPMs is adversely affecting noninfringing uses, whether eligible users may access the works through alternate channels that do not require circumvention, and the legal basis for concluding that the proposed uses are likely to be noninfringing. Similarly, commenters should address any anticipated effect that circumvention would have on the market for or value of the relevant copyrighted works.

E. Proposed Class 5: Audiovisual Works—Personal Playback

Referencing 17 U.S.C. 110(11), added to the Copyright Act by the Family Movie Act of 2005,²²⁸ Jayden Milne petitions for a new exemption to allow circumvention of access controls protecting motion pictures (including television programs, videos, and supplementary motion-picture works) on DVDs, Blu-ray discs, and Ultra HD Blu-ray discs for purposes of “apply[ing] automatic mute or skip instructions to limited portions of audio or video content . . . during contemporaneous private-home

²¹² 2021 Recommendation at 83–98.

²¹³ *Id.* at 94.

²¹⁴ 86 FR 59627, 59633 (Oct. 28, 2021) (2021 final rule); 89 FR 85437, 85440 (Oct. 28, 2024) (2024 final rule).

²¹⁵ See *supra* Section II.H.

²¹⁶ Jamark, LLC (“Jamark”) Class 4(b) Pet. at 2; Stakebake & Stakebake Class 4(b) Pet. at 2.

²¹⁷ Stakebake & Stakebake Class 4(b) Pet. at 2.

²¹⁸ *Id.*

²¹⁹ Jamark Class 4(b) Pet. at 2.

²²⁰ *Id.*

²²¹ *Id.*; Stakebake & Stakebake Class 4(b) Pet. at 2.

²²² See 2021 Register’s Recommendation at 99–101; 2018 Recommendation at 111–28; 2015 Recommendation at 107–26; 2012 Recommendation at 157–66; 2006 Recommendation at 69–72; 2003 Recommendation at 126–41.

²²³ Milne Class 4(c) Pet. at 2; Zerhouane Class 4(c) Pet. at 2.

²²⁴ Milne Class 4(c) Pet. at 2; Zerhouane Class 4(c) Pet. at 2.

²²⁵ Milne Class 4(c) Pet. at 2; Zerhouane Class 4(c) Pet. at 2.

²²⁶ Milne Class 4(c) Pet. at 2; Zerhouane Class 4(c) Pet. at 2.

²²⁷ Milne Class 4(c) Pet. at 2; Zerhouane Class 4(c) Pet. at 2.

²²⁸ Public Law 109–9, sec. 202(a), 119 Stat. 218, 223 (2005).

playback directly from the authorized disc.”²²⁹ The proposed exemption contemplates the use of either “preexisting or household-authored” instructions to filter the work, and would only apply to a particular disc edition when licensed filtering products and services or noncircumventing methods are unavailable.²³⁰ The petition limits circumvention to individual owners “in continuous lawful possession” of the discs, including owners acting “by or at the direction of a member of the owner’s private household.”²³¹

The Office seeks comment on whether this proposed exemption should be adopted, including any proposed regulatory language. Commenters should include information on whether TPMs are adversely affecting noninfringing uses, including whether eligible users may filter discs without circumventing TPMs.

F. Proposed Class 6: Audiovisual Works—Public Domain Works

Jayden Milne petitions for a new exemption to allow circumvention of technological measures that control access to a combination of material—both works protected by copyright and motion pictures in the public domain—for the purpose of copying the public domain material from a “lawfully made and lawfully acquired” DVD, standard Blu-ray disc, or Ultra HD Blu-ray disc for preservation purposes.²³² The petition would limit the exemption to individuals who “lawfully own, rent, borrow, or are otherwise authorized to possess, access, and use the source disc,” and have determined that, after reasonable effort, no equivalent is “reasonably available at a fair price.”²³³ Milne explains that an exemption is needed because access controls continue to prevent circumvention of physical optical discs, despite an increasing number of copyrighted works falling into the public domain since 2019.²³⁴

The Office notes that in the 2012, 2010, and 2003 triennial rulemakings, the Register declined to recommend proposed exemptions for literary and audiovisual works in the public domain and public domain works generally, finding that the circumvention prohibition does not apply to public domain works because they are not protected by copyright law, a

requirement of the prohibition under section 1201.²³⁵ However, the Register acknowledged that “additional questions may arise” and “further information would be required” when technical measures controlling access to public domain material also control access to other works protected by copyright.²³⁶

The Office seeks comment on whether the proposed exemption should be adopted, including any proposed regulatory language. Commenters are encouraged to develop the legal and factual administrative record in their initial submissions, including whether eligible users may access the public domain works through alternative means that do not require circumventing other non-protected formats and examples of access controls protecting a combination of copyrighted and public domain material.

G. Proposed Class 7: Computer Programs—Jailbreaking

Three petitions were filed for new or expanded exemptions covering computer programs, for the purpose of adding, removing, or modifying software on consumer electronic devices (“jailbreaking”).²³⁷ FULU seeks to expand the current exemption for smart TVs to permit the “removal of software,” specifically, automatic content recognition software.²³⁸ In a separate petition, FULU seeks a new exemption for consumer devices to “disable, remove, or prevent the rendering of advertising surfaces . . . pushed onto the user interface . . . after the device was originally sold.”²³⁹ Finally, Public Knowledge and FULU jointly seek a new exemption for “consumer video home-monitoring devices” to “allow the device to route video data to a local server.”²⁴⁰

The Office seeks comment on whether these proposed exemptions should be adopted, including any proposed regulatory language. Commenters should include information clearly describing the computer programs at issue, the TPMs that control access to those programs, and whether the prohibition on circumvention adversely

affects users in their ability to make noninfringing uses of those programs. With respect to the petition for jailbreaking to remove advertising from consumer devices, such as “smart home appliances, smart TVs, voice-assistant devices, e-readers, media players, and car consoles,”²⁴¹ the Office invites comments on whether there are sufficient similarities across devices—in computer programs, TPMs, and adverse effects—to support a single exemption. Comments should also include discussion of the extent to which the proposed activities may or may not be addressed by current regulatory exemptions.

H. Proposed Class 8: Computer Programs—Repair

Several organizations and one individual submitted petitions for new or expanded exemptions relating to diagnosis, maintenance, repair, and modification of software-enabled devices.²⁴² Additionally, the Office received multiple petitions to renew the existing exemption of computer programs in or controlling medical devices or systems for diagnosis, maintenance, or repair of those devices or systems.²⁴³ As discussed, the Office has determined that there is meaningful opposition to this renewal petition.²⁴⁴ Therefore, the Office will evaluate all the proposed repair-related uses of copyrighted works on medical devices and systems together as a potential new exemption.

For reasons of administrative efficiency, the Office has grouped all repair-related proposals into one overall class with two subclasses: one subclass for medical device repair and one covering repair-related proposals for other types of devices and equipment. Commenters may submit a single comment on Class 8, which may address one or both subclasses.²⁴⁵ Supporting evidence must be sufficient to establish an adverse effect on noninfringing uses with respect to each subclass.

Proposed Subclass 8(a): Device and Equipment Repair

FULU, and Public Knowledge and iFixit jointly, filed petitions to expand

²³⁵ 2012 Recommendation at 13–15; 2010 Recommendation at 255–56; 2003 Recommendation at 99–102.

²³⁶ 2012 Recommendation at 15; 2003 Recommendation at 100–01.

²³⁷ FULU Foundation (“FULU”) Class 7 Pet. #1 at 2 (Automatic Content Recognition); FULU Class 7 Pet. #2 at 2 (Advertising); Public Knowledge & FULU Class 7 Pet. at 2; see 37 CFR 201.40(b)(9)–(12) (listing the current jailbreaking exemptions).

²³⁸ FULU Class 7 Pet. #1 at 2 (proposing a modification of 37 CFR 201.40(b)(10)).

²³⁹ FULU Class 7 Pet. #2 at 2.

²⁴⁰ Public Knowledge & FULU Class 7 Pet. at 2.

²⁴¹ FULU Class 7 Pet. #2 at 2.

²⁴² 37 CFR 201.40(b)(13), (15)–(17).

²⁴³ See BMI Medical Device Repair Renewal Pet.; Caylor Medical Device Repair Renewal Pet.; Crothall Medical Device Repair Renewal Pet.; ECMS Medical Device Repair Renewal Pet.; iFixit Medical Device Repair Renewal Pet.; ImageOne Medical Device Repair Renewal Pet.; Shannon Medical Device Repair Renewal Pet.; Trimedx Medical Device Repair Renewal Pet.; 37 CFR 201.40(b)(17).

²⁴⁴ See *supra* Section II.S.

²⁴⁵ See *infra* Section IV.A.3 (discussing page limits for each of the three rounds of written public comments).

²²⁹ Milne Class 5 Pet. at 2.

²³⁰ *Id.*

²³¹ *Id.*

²³² Milne Class 6 Pet. at 2.

²³³ *Id.*

²³⁴ *Id.*

the exemption for computer programs that control devices designed primarily for use by consumers for diagnosis, maintenance, or repair of the device.²⁴⁶ FULU proposes expanding the exemption to permit users to access and modify consumer device programs, which “are typically stored in the device’s firmware or accessed through cloud-based services/servers,” so they can “continue to use the product for its intended purpose” when the manufacturer “(a) has discontinued service or software support essential to its use; or (b) has ceased business.”²⁴⁷ The proposed exemption would “include[] the ability for consumers to maintain, repair, install, or substitute the discontinued software for third-party or community-developed software.”²⁴⁸ Public Knowledge and iFixit propose expanding the consumer device repair exemption, which covers “diagnosis, maintenance, [and] repair,” to include “reconfiguration, continued use, or reuse of the device or system” and extend to “business and enterprise IT devices such as laptops, [secure cell phones,] servers, and storage.”²⁴⁹ They note that it is unclear if the existing exemption applies to devices purchased in bulk for employees or students; and they propose that eligible users of the expanded exemption also include “enterprise, industrial, and government owners and operators of these devices.”²⁵⁰ The Office notes that in 2024, the Register considered a similar proposal and declined to conclude that users were being adversely affected from engaging in noninfringing diagnosis, maintenance, and repair of enterprise IT based on the rulemaking record.²⁵¹ In this cycle, the Office seeks additional examples of how users are adversely affected by the prohibition against circumventing TPMs to engage in the proposed activities.

The Repair Association and iFixit jointly filed a petition proposing a new exemption to maintain and repair “software-enabled fixtures or integrated systems installed on commercial, institutional, and multi-family premises.”²⁵² The exemption would “include[] the ability to maintain, repair, install, or substitute the

discontinued software for third-party or community-developed software.”²⁵³ Eligible users would be owners and operators of the equipment.²⁵⁴ The Office notes that, in previous rulemaking cycles, proponents of broad exemptions to repair commercial or industrial systems cited building systems as examples.²⁵⁵ As the Register previously observed that some users appeared to have adequate alternatives to circumvention for engaging in repair-related activities,²⁵⁶ the Office seeks comments that show the extent to which these activities are being adversely affected by the prohibition against circumvention.

In a second petition, the Repair Association and iFixit jointly propose a new exemption for the circumvention of TPMs that “control software-enabled scientific and laboratory equipment for purposes of diagnosis, maintenance, calibration, and physical repair,” including “installation or substitution of discontinued software with third-party or community-developed software.”²⁵⁷ To the extent necessary for these purposes, the proposed exemption would permit “access and modification” of “copyrighted programs . . . stored in the instrument’s firmware or accessed through manufacturer-controlled software and servers.”²⁵⁸

The Repair Association, iFixit, and Bull Moose Project jointly petition for a new exemption to “permit access and modification to software operating industrial equipment” or “software-enabled manufacturing equipment and integrated manufacturing-facility systems” for diagnosis, modification, maintenance, and repair.²⁵⁹ The Office notes that in the last rulemaking, the Register found that “the rulemaking record does not support a broad proposed class that would cover all commercial and industrial equipment and devices because it is unclear that all such equipment and devices share sufficient commonalities and that the users are similarly situated.”²⁶⁰ In addition, the Register stated that the

“overall the record [was] inconclusive as to whether users [of programmable logic controllers] are being adversely affected.”²⁶¹ Accordingly, the Office seeks comment on whether there are sufficient commonalities among the equipment and systems in the proposed class as well as comments demonstrating the extent to which users are being adversely affected from engaging in repair-related activities.

Proposed Subclass 8(b): Medical Device Repair

As previously discussed, the Office concluded that the renewal petitions for the current medical device repair exemption faced meaningful opposition, and therefore, must be evaluated as a new exemption and proceed through the normal rulemaking process, including the three rounds of public comment. Those renewal petitions are discussed in Section II.S and are incorporated into Class 8(b) with petitions for expanding the existing exemption.

Regarding proposed exemption petitions, Marshall Shannon petitions to expand the exemption to access computer programs that are contained in and control the functioning of medical devices or systems, and related data files, for diagnosis, maintenance, or repair.²⁶² Shannon requests “clarification” that the current exemption already covers or, alternatively, proposes that the exemption be expanded to “expressly cover[] owner-authorized installation, reinstallation, software setup, operating-system and application restoration, relocation, commissioning, calibration, performance verification, service-data access, cybersecurity-related reconfiguration, and return to service for new, used, and resold medical devices.”²⁶³ Shannon further seeks to expand the class of works to include “[c]omputer programs that operate, control, diagnose, monitor, configure, calibrate, install, service, maintain, test, or restore medical devices or systems, including related service interfaces, logs, configuration data, certificates, credentials, utilities, and technical materials” for the purposes of “lawful diagnosis, installation, maintenance, repair, calibration, cybersecurity, or return to service.”²⁶⁴ In addition,

²⁶¹ *Id.* at 155.

²⁶² Shannon Medical Device Repair Renewal Pet. at 3; 37 CFR 201.40(b)(17) (discussing the current medical device or system diagnosis, maintenance, or repair exemption). *See supra* note 134 (explaining that the Office will consider portions of Shannon’s submission that seek “clarification or a modified exemption” as a petition for an expanded exemption).

²⁶³ Shannon Class 8(b) Pet. at 3.

²⁶⁴ *Id.*

²⁵³ *Id.* at 2.

²⁵⁴ *Id.*

²⁵⁵ 2024 Recommendation at 137 n.667 (“automated building management systems”); 2021 Recommendation at 194 (“facility management systems controlling commercial building access”).

²⁵⁶ 2021 Recommendation at 197 n.1083.

²⁵⁷ Repair Association & iFixit Class 8(a) Pet. #2 at 2 (Scientific and Laboratory Equipment).

²⁵⁸ *Id.*

²⁵⁹ Repair Association, iFixit, & Bull Moose Project Class 8(a) Pet. at 2 (listing “programmable logic controllers and process-control systems, production line control systems, industrial robots and motion controllers, additive-manufacturing equipment, semiconductor-fabrication equipment,” and other systems and equipment as examples).

²⁶⁰ 2024 Recommendation at 143.

²⁴⁶ FULU Class 8(a) Pet.; Public Knowledge & iFixit Class 8(a) Pet.; 37 CFR 201.40(b)(15).

²⁴⁷ FULU Class 8(a) Pet. at 2.

²⁴⁸ *Id.*

²⁴⁹ Public Knowledge & iFixit Class 8(a) Pet. at 2.

²⁵⁰ *Id.*

²⁵¹ 2024 Recommendation at 157–58.

²⁵² Repair Association & iFixit Class 8(a) Pet. #1 (Commercial Premises Equipment) (listing “commercial HVAC, battery energy-storage systems, elevator systems, building management systems, and other similar equipment” as examples).

because Trimedx lists “regulatory compliance” among the purposes covered by the existing exemption notwithstanding that that use is not expressly covered by the exemption, the Office considers it here as a proposed expansion.²⁶⁵

The Office seeks comments and documentary evidence that explain, under the current exemption and proposed expansions, the type of works (*i.e.*, types of computer programs and related data files) that would be covered; how those works are configured on medical devices and systems; for each type of work, whether the current and proposed uses are noninfringing; and how the adverse effects analysis applies to the different types of works and uses. Commenters should submit evidence specific to the issues and circumstances raised by the proposed exemption, identify any materials from prior proceedings on which they rely, and explain how those materials bear on the proposed exemption. The Office will assess the comments and evidence developed in the current proceeding, together with relevant records from previous proceedings, in deciding whether and to what extent to recommend adoption of the proposed exemption.²⁶⁶

Commenters should explain the extent to which each proposed activity would require expansion of the current regulatory exemption for medical device repair. When addressing each proposed activity or type of work that is not covered by the current exemption, commenters should explain why that particular use is likely to be noninfringing as well as how that use is adversely affected by the prohibition against circumvention. Commenters are also encouraged to submit documentary evidence demonstrating how medical device software and other copyrighted works that a petitioner seeks to access via circumvention are configured.²⁶⁷

Finally, regarding the proposed new exemption petitions for each subclass,

the Office notes that most of them include “modification” among the proposed uses. Outside of the vehicle repair exemption, which permits “lawful modification of a vehicle or vessel function,”²⁶⁸ the Register has consistently declined to recommend that repair-related exemptions extend to device modification due to uncertainty about whether modifications of device software, as opposed to physical modifications, would infringe the software owner’s right to prepare derivative works.²⁶⁹ Commenters for each subclass should explain whether “modification” is likely to be noninfringing for the various device types described in the petitions. Because three of the current exemptions define “repair” as “the restoring of the device to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device,”²⁷⁰ commenters should also address whether this definition should apply to any proposed exemption for Class 8(a) and 8(b) when discussing their proposed regulatory language.

I. Proposed Class 9: Video Games—Operating System Incompatibility

Ken Austin petitions for a new exemption to permit circumvention by “individual owners of video games” which have “DRM [that] no longer function[] properly” due to “incompatibility or other errors” with modern computers’ operating systems.²⁷¹ The petition explains that “many old [video] games released for Windows on CD and DVD” rely on DRM, such as SafeDisc, that “no longer work[] on modern versions of [Windows] operating system[s],” due to operating systems flagging games’ TPMs as security threats.²⁷² Austin also states that a subset of these games “lack official patches to remove or repair the faulty DRM, or new, working versions that are reasonably available for purchase.”²⁷³

The Office notes that last cycle it considered and rejected a substantively identical proposal regarding video games that were no longer functional due to incompatibility with computer

operating systems.²⁷⁴ That petition “was not supported by a sufficient record in [last cycle’s] proceeding,” and the Office lacked evidence to determine that “the harm identified . . . involve[d] ‘distinct, verifiable and measurable impacts’ occurring in the marketplace.”²⁷⁵ The Office encourages proponents to develop a more robust administrative record. Commenters should describe with specificity the relevant TPMs and whether their presence is adversely affecting noninfringing uses, including identifying whether eligible users may access the software through alternate channels that do not require circumvention, the basis for concluding that the proposed uses are likely to be noninfringing, and examples of games that may be subject to the proposed exemption. In general, the Office seeks comment on whether the proposed exemption should be adopted, including any proposed regulatory language.

J. Proposed Class 10: Video Games—Network Play

Dan Elkins petitions to expand the current exemption covering continued play of video games.²⁷⁶ The petition proposes that “personal, local gameplay” be expanded to include online gameplay and permit circumvention of access controls on lawfully acquired games “to interoperate with [an] independently implemented replacement network infrastructure” when the copyright owner has “discontinued, materially degraded, or replaced external server functionality originally used by those games” without providing “materially equivalent original functionality.”²⁷⁷ The proposed expansion would not permit “unauthorized reproduction or distribution of games, unauthorized access to copyright-owner servers, or copying of proprietary server software” and would leave “[m]odern entitlement and authentication mechanisms” intact.²⁷⁸

The Office notes that when considering the original exemption, the Register concluded that “proponents ha[d] not satisfied their burden with respect to a need for an exemption for continued online multiplayer play.”²⁷⁹ The Office seeks comment on whether the proposed expansion should be

²⁶⁵ Trimedx Medical Device Repair Renewal Pet. at 4; *see supra* note 134 (discussing the Office’s treatment of Trimedx’s renewal petition discussing “regulatory compliance” as a proposed expansion and beyond the scope of the streamlined renewal process).

²⁶⁶ *See* Section 1201 Study at 110 (recognizing the Office’s discretion to take administrative notice of evidence); *id.* at 112 (including evidence administratively noticed by the Office in the rulemaking record); *id.* at 143 n.776 (explaining, in its discussion of renewal, that *de novo* assessment can draw on a prior record if parties provide a basis to assess its continuing relevance).

²⁶⁷ *See MITA*, slip op. at 13 (concluding that there was no record in the 2018 and 2021 triennial rulemakings to support “the proposition that there is a distinct body of repair software independent from the clinical-operation software and that it occupies its own standalone market”).

²⁶⁸ 37 CFR 201.40(b)(13).

²⁶⁹ *See* 2024 Recommendation at 158; 2021 Recommendation at 204–06; 2018 Recommendation at 206–08.

²⁷⁰ 37 CFR 201.40(15)(ii), (16)(ii); *see* 37 CFR 201.40(17)(ii) (applying to a “device or system”); *cf.* 17 U.S.C. 117(d).

²⁷¹ Austin Class 9 Pet. at 2.

²⁷² *Id.*

²⁷³ *Id.*

²⁷⁴ *See* 2024 Austin Class 6(b) Pet.; 2024 Recommendation at 172–73.

²⁷⁵ 2024 Recommendation at 172–73 (quoting Commerce Comm. Report at 37).

²⁷⁶ Elkins Class 10 Pet. at 2; 37 CFR 201.40(b)(19)(i)(A).

²⁷⁷ Elkins Class 10 Pet. at 2.

²⁷⁸ *Id.*

²⁷⁹ 2015 Recommendation at 337, 345–46.

adopted, including any proposed regulatory language. Commenters responding to this petition should include information on whether there have been new factual or legal developments that would support an expansion and whether its scope should be modified, including whether alternate methods to access online play exist that do not require circumvention. Comments should also describe with specificity the relevant TPMs, their location, and whether the prohibition on circumvention is adversely affecting noninfringing uses, the methods of circumvention sought, whether persons “developing or operating replacement infrastructure” for owners are users within the meaning of 1201(a)(1), and examples of games potentially subject to the exemption.²⁸⁰ In general, the Office seeks comment on whether the proposed exemption should be adopted, including any proposed regulatory language.

Proposed New or Expanded Exemptions Not Considered

As stated in the NOI, the Office will not at the NPRM phase “reject any petitioned-for exemption unless it fails to meet the threshold requirements of section 1201(a).”²⁸¹ After reviewing the petitions that seek new exemptions, the Office observes that two petitions cannot be granted as a matter of law, as they fail to allege “a particular class of works” or “distinct, verifiable and measurable impacts” on noninfringing uses.²⁸²

The first petition proposes that “researchers, journalists, educators, students, investigators, legal professionals, archivists, nonprofit workers, and individuals” be permitted to circumvent “online audiovisual works, web pages, images, PDFs, and related metadata” for “documentation, research, evidence preservation, citation, accessibility, archival review, journalism, education, legal

investigation, or personal recordkeeping” purposes.²⁸³ The relevant barriers to access include TPMs and “streaming-only delivery, expiring URLs, platform restrictions, embedded players, account-gated access, anti-download controls, disappearing or modified online content, and formats that prevent users from saving evidence-quality local copies of materials they can lawfully view.”²⁸⁴

The second petition proposes “a class-wide remedy for motion pictures on protected consumer optical discs” where users, “[un]limit[ed] . . . by ownership or occupation,” can circumvent the works for unrestricted purposes, including “private disc-present playback without a fixed copy; private-home filtering under [section] 110(11); criticism or comment using short portions; disability access; public-domain-only use; qualifying replacement or preservation; and restoration of a specifically promised bundled copy.”²⁸⁵ The relevant barriers to access include CSS on DVDs, AACs on HD DVD and standard Blu-ray discs, and AACs2 on Ultra HD Blu-ray discs.²⁸⁶

These proposed exemptions are beyond the Librarian’s authority to adopt because they do not meet the statutory requirements of an exemption authorized by section 1201. As previously discussed, section 1201 requires that any exemption adopted as part of the triennial rulemaking be limited to “a particular class of copyrighted works.”²⁸⁷ Legislative history explains that Congress intended the phrase to encompass “a narrow and focused subset of the broad categories of works . . . identified in [s]ection 102 of the Copyright Act.”²⁸⁸ Therefore, the Office uses the section 102 categories as a starting point and refines the proposed classes by other criteria, such as the types of TPMs used or the types of uses. As Congress explained, while the category of “literary works” under

section 102(a)(1) “embraces both prose creations such as journals, periodicals or books, and computer programs of all kinds,” “[i]t is exceedingly unlikely that the impact of the prohibition on circumvention of access control technologies will be the same for scientific journals as it is for computer operating systems.”²⁸⁹ Congress concluded the “two categories of works . . . do not constitute a single ‘particular class’ for purposes of” section 1201(a)(1).²⁹⁰ Neither the first petition (which proposes an exemption for all or nearly all works available online) nor the second petition (which proposes an exemption for all motion pictures with an express lack of limits as to users and uses)²⁹¹ propose an exemption for a single particular class for the purposes of section 1201.

“Determining the appropriate scope of a ‘class of works’ for an exemption may also involve consideration of the adverse effects an exemption may have on the market for or value of copyrighted works.”²⁹² Adverse effects may be shown by demonstrating “distinct, verifiable and measurable impacts” on noninfringing uses.²⁹³ The second petition contains multiple undefined uses that lack any clear bounds and is premised on the concept that they should not have to show adverse effects use-by-use. The Register and the Librarian are unable to analyze the adverse effects of unbounded uses in order to determine whether an exemption could be granted.²⁹⁴ The Office’s determination not to offer this petition for comment does not foreclose consideration of any of the listed uses: the petition itself states that “each narrower alternative can stand alone,”²⁹⁵ and each of those uses were filed by the same petitioner as separate petitions for new exemptions, which the Office has put forth for consideration above.²⁹⁶

Because these two petitions fall outside the scope of exemptions that the Register can recommend and the Librarian can adopt under section 1201, the Office declines to put these petitions forward for public comment.

²⁸⁰ Elkins Class 10 Pet. at 2.

²⁸¹ NOI at 34798 (discussing an overview of the triennial rulemaking process) (citing 79 FR 73856, 73859 (Dec. 12, 2014)).

²⁸² 17 U.S.C. 1201(a)(1)(B); Commerce Comm. Report at 37. The Register has repeatedly declined to recommend proposed exemptions that have failed to define the class of works to be covered with sufficient particularity. *See, e.g.*, 2018 Recommendation at 131–32; 79 FR at 73859; 2006 Recommendation at 17–19; *see also* 85 FR at 65308–09 (allowing a proposed exemption that sought to permit circumvention of access controls across all classes of copyrighted works for accessibility purposes to proceed to the public comment phase “[i]n light of [its] important public policy considerations” and subject to substantial provisions regarding the need to develop proposed exemptions within the Librarian’s authority to adopt).

²⁸³ MuCache Multiple Works Pet. at 2.

²⁸⁴ *Id.*

²⁸⁵ Milne Class-Wide Relief Pet. at 2.

²⁸⁶ *Id.*

²⁸⁷ 17 U.S.C. 1201(a)(1)(C).

²⁸⁸ Commerce Comm. Report at 38; *see also id.* at 36 (explaining that the rulemaking “allow[s] the enforceability of the prohibition against the act of circumvention to be *selectively* waived, for limited time periods, if necessary to prevent a diminution in the availability to individual users of a *particular category* of copyrighted materials” (emphasis added)); Staff of H. Comm. on the Judiciary, 105th Cong., Section-by-Section Analysis of H.R. 2281 as Passed by the United States House of Representatives on August 4th, 1998, at 6 (“[T]he main focus of the rulemaking proceeding will be on whether a substantial diminution of that availability is *actually occurring* in the market for *particular classes* of copyrighted works.” (emphasis added)).

²⁸⁹ Staff of H. Comm. on the Judiciary, 105th Cong., Section-by-Section Analysis of H.R. 2281 as Passed by the United States House of Representatives on August 4th, 1998, at 7.

²⁹⁰ *Id.*

²⁹¹ Milne Class-Wide Relief Pet. at 2 (“These uses are examples of the recurring problem, not limits on the primary request.”).

²⁹² 2021 Recommendation at 9.

²⁹³ Commerce Comm. Report at 37.

²⁹⁴ *Id.*

²⁹⁵ Milne Class-Wide Relief Pet. at 2.

²⁹⁶ *See supra* Sections III.B–F.

IV. Phases of the Tenth Triennial Rulemaking

A comprehensive administrative record for the section 1201 triennial rulemaking is developed through written comments, public hearings, post-hearing questions, and *ex parte* meetings. The Register then makes her recommendation to the Librarian, who adopts a final rule. Each future phase of the administrative process is described below.²⁹⁷

Late filed submissions in *any* phase of the rulemaking, including amendments or supplements thereto, will not be accepted without a showing of good cause, and their acceptance is subject to the Office's discretion.²⁹⁸ Participants should timely file complete comments using the appropriate form. Informational guides explaining section 1201 and the rulemaking process can be found on the Office's section 1201 rulemaking web page at <https://www.copyright.gov/1201>.

A. Public Comment Phase

This NPRM initiates the second phase of the triennial rulemaking: the public comment phase, which consists of three rounds of written public comments regarding the petitions for new exemptions and any meaningfully opposed renewal petitions. Commenters should present their complete legal and evidentiary case in support of or in opposition to the proposed exemption. In this proceeding, the Office is initiating a page limit requirement for each of the three rounds of written public comments.

1. Substance of Comments

Parties wishing to address proposed exemptions, including the one meaningfully opposed renewal petition, in written comments should familiarize themselves with the substantive legal and evidentiary standards for the granting of an exemption under section 1201(a)(1), as described in the **ADDRESSES** section of this notice above. In addressing factual matters, commenters should be aware that the Office favors specific, real-world examples supported by evidence over hypothetical observations. Commenters should describe with specificity the TPMs that control access to the work, the method of circumvention of those TPMs, whether their presence is adversely affecting noninfringing uses, and whether eligible users may engage

in the proposed use through alternate means that do not require circumvention. In general, the Office seeks comment on whether these proposed exemptions should be adopted, including any proposed regulatory language.

Commenters' legal analysis should explain why the proposal meets or fails to meet the criteria for an exemption under section 1201(a)(1), including why the uses sought are or are not noninfringing as a matter of law. The legal analysis should also discuss statutory or other legal provisions that could impact the necessity for or scope of the proposed exemption. Legal assertions should be supported by statutory citations, relevant case law, and other pertinent authority. In cases where a class proposes to expand an existing exemption, participants should focus their comments on the legal and evidentiary bases for modifying the exemption, rather than the underlying exemption. As discussed above, the Register intends to recommend all but one current temporary exemption for renewal, which was meaningfully opposed. That petition will be subject to three rounds of public comment.

2. Comment Submission Instructions and Three Rounds of Written Public Comment

To ensure a clear and definite record for each of the proposals, separate submissions must be submitted for each proposed class and not combined. Accordingly, the same party may submit multiple written comments on different proposals. The Office acknowledges that the requirement of separate submissions may require commenters to repeat certain information across multiple submissions, but concludes that the administrative benefits of creating a self-contained, separate record for each proposal justify the modest added effort.

The first round of public comment is limited to submissions from proponents (*e.g.*, those who proposed new exemptions during the petition phase or provide the legal and evidentiary basis for them during the public comment phase) and other members of the public who support the adoption of a proposed exemption. Those who neither support nor oppose an exemption may also comment with pertinent information. Proponents should present their complete affirmative case for an exemption during the initial round of public comment, including complete legal and evidentiary support.

The second round of public comment seeks comments from those who oppose a proposed exemption; these commenters should present the full

basis for their opposition, including complete legal and evidentiary support. The third round of public comment is limited to reply comments from those permitted to comment in the first round, addressing arguments and evidence presented by others during prior rounds. Reply comments should not raise new issues or evidence.²⁹⁹

3. Comment Page Limit

In this proceeding, the Office is establishing a page limit for each of the three rounds of written public comments per class. Each commenter may submit a maximum of twenty-five (25) pages, in at least 12-point type, per class per round of comments, except for Proposed Class 8: Computer Programs—Repair, where comments submitted for each subclass should total twenty-five (25) pages or less.³⁰⁰ The limitation applies to all comments, including jointly submitted comments.³⁰¹ This page limit does not apply to documentary evidence; specifically, those containing material authored by persons other than the comment submitters (*e.g.*, affidavits, exhibits, letters).

Commenters wishing to exceed the page limit must contact the Office, using the contact information contained within the **FOR FURTHER INFORMATION CONTACT** section of this NPRM, prior to submission.³⁰² The decision to grant a commenter's request is subject to a showing of good cause and at the Office's discretion.

The Office has determined that the authority to impose this page limit is within section 1201(a)(1) and is further supported by its accompanying legislative history. As the Office stated in its *Section 1201 of Title 17* study, "section 1201 appears to give the Office considerable flexibility to define and

²⁹⁹ Newly raised issues and evidence are not permitted in the third round of written public comments or in any subsequent rulemaking phase. NOI at 34796.

³⁰⁰ The Office established this page limit after reviewing comments from the previous two triennial rulemakings and determining that the overwhelming majority of comments were fewer than ten pages (excluding documentary evidence) and reviewing other federal agencies' page limits. *See, e.g.*, 49 CFR 553.21, 800.37 (discussing the National Highway Traffic Safety Administration's and the National Transportation Safety Board's fifteen-page limit for comments submitted in response to agency rulemakings). The page limit applies separately to each proposed class in each round. Pages submitted in one class do not count toward the limit in any other class.

³⁰¹ A submitter who has reached the page limit for a class may not file, individually or jointly with another, any additional submission addressing that class during the same comment round.

³⁰² *See supra* page 2.

²⁹⁷ *See also* NOI at 34796 (discussing an overview of the triennial rulemaking process).

²⁹⁸ *See, e.g.*, 2024 Recommendation at 20 n.72 ("[T]he Register has no obligation to consider untimely comments.").

tailor the rulemaking process.”³⁰³ The relevant statutory provisions do not “mandate [the] specific processes that the Register must follow” for conducting the rulemaking,³⁰⁴ beyond “report[ing] and comment[ing] on . . . her views in making” recommendations to the Librarian.³⁰⁵ Corresponding legislative history also evidences Congress’s intent that the specific rulemaking procedures beyond “permit[ting] interested persons an opportunity to participate through the submission of written statements, oral presentations at one or more of the public hearings, and the submission of written responses to the submissions or presentations of others,” lie within the Office’s purview.³⁰⁶ The Office concludes that the page limit is consistent with its informal rulemaking requirements under the Administrative Procedure Act³⁰⁷ and is a needed change to improve the rulemaking

³⁰³ Section 1201 Study at 107.

³⁰⁴ *Id.* at 24.

³⁰⁵ 17 U.S.C. 1201(a)(1)(C).

³⁰⁶ H.R. Rep. No. 106–464, at 149 (1999); *see also* H.R. Rep. No. 105–796, at 64 (1998) (“It is the intention of the conferees that, as is typical with other rulemaking under title 17, and in recognition of the expertise of the Copyright Office, the Register of Copyrights will conduct the rulemaking, including providing notice of the rulemaking, seeking comments from the public, consulting with the Assistant Secretary for Communications and Information of the Department of Commerce and any other agencies that are deemed appropriate, and recommending final regulations in the report to the Librarian.”).

³⁰⁷ 5 U.S.C. 553(c) (requiring, absent specific exceptions, that an agency “give interested persons an opportunity to participate in the rule making through submissions of written data, views, or arguments”); *see also* H.R. Rep. No. 106–464, at 149 (explaining that the removal of previous draft legislative language was “a technical correction to clarify the intent of Congress that the Copyright Office shall conduct the [section 1201] rulemaking . . . as an informal rulemaking proceeding”).

process, “while maintaining procedural rules necessary for it to administer the rulemaking efficiently within the statutorily mandated period.”³⁰⁸

B. Public Hearings Phase

After the public comment phase, the Office will hold online public hearings in spring 2027. The hearings will focus on unresolved issues material to proposed exemptions that the Office finds unclear or underdeveloped in the written record, and may offer the opportunity to introduce demonstrative evidence. Demonstrative evidence is limited to demonstrations that illustrate uses, technological measures, or methods of circumvention already described in the written record; it is not a vehicle for new factual showings. Participants may not submit additional written evidence during or after the hearings or introduce new evidence or arguments at the hearings. A separate notice providing details about the hearings and how to participate will be published in the **Federal Register**.

1. Post-Hearing Questions

Following the hearings, the Office may direct written questions to specific participants to discuss discrete issues in particular classes, including suggestions regarding regulatory language. Although submission deadlines are provided, responses to these questions are voluntary. Responses will be posted on the Office’s website as part of the public record.

2. Ex Parte Communication

As in prior proceedings, the Office will permit *ex parte* communications after the conclusion of the hearings. Participating parties will be required to

³⁰⁸ Section 1201 Study at 107.

follow the Office’s regulation on *ex parte* communications.³⁰⁹ No *ex parte* communications with the Office regarding this proceeding will be permitted before the hearings have concluded or at any time outside of the permitted period. The Office will identify the specific time period it will accept requests for *ex parte* communications in the notice it publishes to initiate the public hearings phase.

C. Register’s Recommendation and Librarian’s Final Rule

The Office will analyze the complete administrative record, which may include submissions from other parts of the federal government.³¹⁰ Following consultation with the National Telecommunications and Information Administration, the Register will issue her written recommendation to the Librarian as to which exemptions are warranted, including proposed regulatory text for adoption as a final rule. The Librarian, after consideration of the Register’s recommendation, will adopt a final rule announcing any exemptions.³¹¹

Dated: October 23, 2026.

Emily L. Chapuis,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2026–21939 Filed 10–27–26; 8:45 am]

BILLING CODE 1410–30–P

³⁰⁹ *See* 37 CFR 201.1(d), 205.24; *see generally* *Ex Parte Communications*, U.S. Copyright Office, <https://www.copyright.gov/rulemaking/ex-parte-communications/> (last visited Oct. 23, 2026).

³¹⁰ *See* *Letters Between the U.S. Copyright Office and Other Agencies*, U.S. Copyright Office, <https://www.copyright.gov/1201/2024/USCO-letters/> (last visited Oct. 23, 2026); Section 1201 Study at 150–51.

³¹¹ 89 FR at 85445–50.

Notices

Federal Register

Vol. 91, No. 207

Wednesday, October 28, 2026

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology.

Comments regarding this information collection received by November 27, 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.

Forest Service

Title: Equal Opportunity Compliance Review Reporting Tool.

OMB Control Number: 0596–0215.

Summary of Collection: All Federal agencies and the entities receiving Federal financial assistance are prohibited from discriminating in the delivery of programs and services. Agencies must comply with equal opportunity laws, Title VI of the Civil Rights Act of 1964, as amended; Title IX of the Education Amendments Act of 1972; The Age Discrimination Act of 1975, as amended; Section 504 of the Rehabilitation Act of 1973, as amended; and Executive orders prohibiting discrimination in the delivery of all programs and services to the public. Federal agencies and entities receiving Federal Financial Assistance are prohibited from discriminating. Federal Financial Assistance is defined as, "Federal monies given by grants, cooperative agreements, commercial special use permits, training, loan/temporary assignment of Federal personnel, loan/use of Federal property at below market value."

The equal opportunity laws require agencies to conduct compliance reviews to ensure that entities receiving Federal Financial Assistance from the government are adhering to the nondiscrimination statutes. The statutes require that prior to awarding support or issuing permits, the Federal government shall conduct pre-award reviews to ensure that potential recipients understand their responsibilities to provide services equitable pursuant to the law. Thereafter, during the partnership with the agency, ongoing monitoring will take place to ensure the public is being served without any barriers or discrimination.

Need and Use of the Information: Forest Service employees will use FS–1700–6A, Equal Opportunity Compliance Review Record, to document shared non-discrimination obligations and collect information regarding actions taken by recipients of Federal financial assistance to ensure the public receives services without discrimination or barriers to access. Optional form B documents that recipients' employees understand their customer service role and optional form

C is for customers' awareness of their rights of non-discrimination.

Collection form FS–1700–6A, Equal Opportunity Compliance Review Record, will occur during face-to-face meetings or telephone interviews conducted by a Forest Service employee as part of the pre-award and post-award process. The pre-award interview will take place prior to the signing of a cooperative agreement, domestic grant, commercial special use permit award or similar where a non-discrimination clause appears in the agreement. The post award interview will take place either on a five (5) or 10-year basis as instructed in Forest Service Handbook (FSH) 1709.11, Chapter 70 or upon report/discovery of discrimination.

Only general statistical information will be summarized and shared in the Health and Human Services (HHS) and Department of Justice (DOJ) annual report. However, if a report or discovery of a discrimination complaint is identified then it will be reported to the USDA Office of the Assistant Secretary for Civil Rights.

Monitoring reviews have been a responsibility of the Federal government since 1964 and continue to be an obligatory activity as outlined in 28 Code of Federal Regulations 42.401–415 and 7 Code of Federal Regulation 15.5. Without the ability to monitor recipients of Federal financial assistance, the Forest Service would not be able to ensure compliance with the civil rights laws, statutes, and current Executive Orders (E.O.). The Agency would not be aware of potential discriminatory practices. Absence of this form leaves the American people and the public that we serve vulnerable to non-merit-based decisions and discrimination.

Description of Respondents: Business or other for-profit; Not-for-profit Institutions; State, Local or Tribal Government.

Number of Respondents: 11,625.

Frequency of Responses: Recordkeeping; Reporting; Annually.
Total Burden Hours: 52,313.

Forest Service

Title: Infrastructure Investment and Jobs Act Financial Assistance to Facilities that Purchase and Process Byproducts for Ecosystem Restoration (CFDA 10.725) Wood Products Infrastructure Assistance (WPIA).

OMB Control Number: 0596–0254.

Summary of Collection: USDA Forest Service is delivering the Wood Products Infrastructure Assistance (WPIA) as part of Section 40804(b)(3) of the Infrastructure Investment and Jobs Act Public Law 117–58 (11/15/2021) which directs the USDA Forest Service to provide financial assistance to an entity seeking to establish, reopen, expand, or improve a sawmill or other wood processing facility in close proximity to a unit of federal or Indian land that has been identified as high or very high priority for ecological restoration. According to 2 CFR part 200 and Forest Service Handbook 1509.11, Chapter 20, there is certain narrative and budget information required for the Agency to determine if the project meets the legislative requirements and if the costs are reasonable, allocable, allowable, and necessary for the project. In particular, collection of information is necessary to ascertain if applicants seeking financial assistance do in fact operate facilities in close proximity to a unit of federal or Indian land that has been identified as high or very high priority for ecological restoration.

Need and Use of the Information: Eligible applicants are for-profit entities; state, local governments; Indian Tribes; school districts; community, not-for-profit organizations; institutions of higher education; and special purpose districts (e.g., public utilities districts, fire districts, conservation districts, and ports).

Applications will be submitted to via email by the date and time as listed in the Notice of Funding Opportunity at *Grants.gov*; searchable and identifiable by the catalog of domestic federal assistance (CFDA) number 10.725. The Forest Service State & Private Forestry will receive, review, and track all applications.

Description of Respondents: State, Local, Tribal governments.

Number of Respondents: 197.

Frequency of Responses: Annually.

Total Burden Hours: 1,034.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026–21993 Filed 10–27–26; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and 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 these information collections are best assured of having their full effect if received by November 27, 2026. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: Livestock Mandatory Reporting Act of 1999.

OMB Control Number: 0581–0186.

Summary of Collection: The Livestock Mandatory Reporting Act of 1999 (1999 Act) authorizes the collection and reporting of information on the prices and quantities of livestock and livestock products. In 2001, the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) implemented the Livestock Mandatory Reporting (LMR) program as required by the 1999 Act [Pub. L. 106–78; 113 Stat. 1188; 7 U.S.C. 1635–1636(i)]. On September 30, 2015, the Agriculture Reauthorizations Act of 2015 (2015 Reauthorization Act) reauthorized LMR for an additional five years, until September 30, 2020. The Reauthorization was extended through September 30, 2021, in the Consolidated Appropriations Act of 2021 and currently extended through September

30, 2022, in the Consolidated Appropriations Act of 2022.

The request for information, as mandated by the 1999 Act and amended under the 2015 Reauthorization Act, requires livestock packing plants that annually slaughter an average of 125,000 cattle, 100,000 barrows and gilts, or 200,000 sows and boars; or slaughter or process an average of 35,000 lambs to report information as described in the 1999 Act. In addition, the 1999 Act, as amended under the 2015 Reauthorization Act, requires importers that annually import an average of 1,000 metric tons of lamb meat products to report information as described in the 1999 Act.

Need and Use of the Information: The information collection and recordkeeping requirements mandated by the 1999 Act are essential for AMS to administer a mandatory reporting program of livestock and livestock products. Using the information submitted by packers and importers, AMS publishes over 100 daily, weekly, and monthly reports covering market transactions for fed cattle, swine, lamb, beef, lamb meat, and pork. Collection is accomplished through electronic means, and AMS reports the information up to three times daily and once weekly. The information collected is necessary for the proper performance of AMS functions concerning mandatory reporting of livestock market information.

Description of Respondents: Business or other for-profit.

Number of Respondents: 118.

Frequency of Responses: Reporting; Weekly; Other (Daily).

Total Burden Hours: 23,712.

Agricultural Marketing Service

Title: Export Inspection and Weighing Waiver for High-Quality Specialty Grains Transported in Containers Under the Authority of the United States Grain Standards Act.

OMB Control Number: 0581–0306.

Summary of Collection: The United States Grain Standards Act (USGSA), with few exceptions, requires official certification of export grain sold by grade. The regulations promulgating the USGSA require specific information collection and record-keeping necessary to enforce provisions in the statute. On July 29, 2011, Federal Grain Inspection Service (FGIS) published a final rule in the **Federal Register** (76 FR 45397) to amend the regulations under the USGSA to make permanent a waiver that expired on July 31, 2012 for high quality specialty grains exported in containers from the mandatory inspection and weighing requirements

of the USGSA. To ensure that exporters of high-quality specialty grains comply with this waiver, FGIS is asking exporters to maintain records generated during their normal course of business that pertain to these shipments and make these documents available to the FGIS upon request. FGIS has no other means available to monitor the grain industry's compliance with provisions of this waiver.

Need and Use of the Information: To comply with the waiver of the mandatory inspection and weighing requirement, FGIS is asking exporters of high quality specialty grains transported in containers to maintain records generated during their normal course of business that pertain to these shipments and make these documents available to FGIS upon request. Experience has shown that the U.S. grain industry maintains grain contracts that specify quality parameters agreed to by buyers and sellers of grain. FGIS believes that grain contracts would provide sufficient information to determine if exporters of high-quality specialty grain are complying with the waiver. This information collection requirement is essential for FGIS to enforce provisions set forth in the USGSA. FGIS intends to request copies of the relevant documents annually to ensure compliance with this waiver. FGIS also will require exporters to maintain records for a 3-year period.

Description of Respondents: Business or other for-profit.

Number of Respondents: 40.

Frequency of Responses: Recordkeeping.

Total Burden Hours: 240.

Agricultural Marketing Service

Title: National Organic Program: Strengthening Organic Enforcement (SOE).

OMB Control Number: 0581-0321.

Summary of Collection: The National Organic Program (NOP) is authorized by the Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501 *et seq.*). The Agricultural Marketing Service (AMS) administers the NOP. Under the NOP, AMS oversees national standards for the production and handling of organically produced agricultural products. The NOP is issuing a final rule to amend its regulations.

The OFPA authorizes the improvement and strengthening of organic production and handling production standards (7 U.S.C. 6513(c)) to strengthen oversight and enforcement of the production, handling, and sale of organic agricultural products. The NOP identified the need for many of the

amendments as part of its direct experience in administering this program, particularly via complaint investigations and audits of certifying agents. Other final amendments are based on recent amendments to the OFPA included in the Agriculture Improvement Act of 2018; the recommendations of a 2017 Office of Inspector General audit; multiple recommendations of the federal advisory committee to the NOP, the National Organic Standards Board (NOSB), from 2002 to 2018; and industry stakeholder feedback.

This final rule strengthens enforcement with amendments and new requirements to the USDA organic regulations. The amendments in this final rule are intended to: (1) strengthen organic control systems; (2) improve organic import oversight; (3) clarify organic certification standards; and (4) enhance supply chain traceability. Specific provisions require: a new group of handlers, brokers and traders, to become certified as organic in order to trade or broker certified organic products; additional information on nonretail labels; new procedures to strengthen traceability; the use of federated organic certificates; unannounced on-site inspections; import certificates on all imported product; additional inspector training and qualifications; more review of foreign conformity systems; and the development and expansion of electronic data and document management systems governing organic certification of operations and traceability through transactions and trade, and clarified compliance and appeals processes for certifying agents and organic operations.

Need and Use of the Information: In general, the information collected is used by USDA, State program governing officials, and certifying agents. It is created and submitted by accredited certifying agents, certified organic producers and handlers, those seeking or maintaining accreditation or certification, organic inspectors, State and foreign program officials, and parties interested in changing the National List. Additionally, accredited certifying agents, certified organic producers and handlers, those seeking accreditation or certification, and State and foreign program officials have procedures and space for recordkeeping.

Description of Respondents: Businesses or other for-profits.

Number of Respondents: 51,091.

Frequency of Responses: On occasion: Annually.

Total Burden Hours: 231,617.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026-21992 Filed 10-27-26; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and 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 27, 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.

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Rural Business-Cooperative Service

Title: 7 CFR 1951-R, Rural Development Loan Servicing.

OMB Control Number: 0570-0015.

Summary of Collection: The Rural Development (RD) Loan Servicing was legislated in 1985 under Section 1323 of

the Food and Security Act of 1985. This action is needed to implement the provision of Section 407 of the Health and Human Services Act of 1986, which amended Section 1323 of the Food and Security Act of 1985. Subpart R of 7 CFR part 1951 contains regulations for servicing and liquidating loans made by Rural Development under the Intermediary Relending Program (IRP) and the Rural Microentrepreneur Assistance Program (RMAP) to eligible intermediaries and applies to ultimate recipients and other involved parties.

Need and Use of the Information: Rural Development has determined that the financial reporting requirements are necessary to provide the Agency with current information in order to monitor the program, to make various reporting requirements to Congress, and for program innovation and expansion under the Government's Performance Review.

Servicing of the IRP is administered by RBCS in Washington, DC, which will be the primary user of the information collected, which is vital to RBS for prudent loan servicing, credit decisions, and reasonable program monitoring.

Description of Respondents: Non-profit corporations, public agencies, Tribal councils and cooperatives.

Number of Respondents: 53.

Frequency of Responses: Reporting: On occasion; Quarterly; Semi-annually; Annually.

Total Burden Hours: 1,276.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026-21994 Filed 10-27-26; 8:45 am]

BILLING CODE 3410-XY-P

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Solicitation Request for Applications for Memberships to the National Agricultural Research, Extension, Education, and Economics (NAREEE) Advisory Board and Citrus Disease Subcommittee (CDS)

AGENCY: Research, Education, and Economics, United States Department of Agriculture (USDA).

ACTION: Solicit applications for memberships for the National Agricultural Research, Extension, Education, and Economics (NAREEE) Advisory Board and Citrus Disease Subcommittee (CDS).

SUMMARY: In accordance with the Federal Advisory Committee Act, the U.S. Department of Agriculture (USDA)

announces the opening of the solicitation for applications to fill vacancies on the National Agricultural Research, Extension, Education, and Economics (NAREEE) Advisory Board and the Citrus Disease Subcommittee (CDS) for Fiscal Year 2027.

DATES: Visit the NAREEE Advisory Board website: <https://nareeeab.ree.usda.gov/membership> to review a complete list of the Board and committee and subcommittee membership categories. If you wish to be considered for the seats listed above, electronic applications should be submitted by close of business on Monday, November 30, 2026. Applications submitted through the mail should be postmarked no later than Monday, November 30, 2026.

ADDRESSES: Please submit a complete nomination package with the nominee's name, resume or CV, completed and signed Form AD-755, and any letters of support or recommendation must be submitted via one of the following methods: (1) Email to NAREEE@usda.gov; or (2) By mail delivery service to Attention, Richard Derksen, NAREEE Advisory Board, U.S. Department of Agriculture, 1400 Independence Avenue SW, Room 6020, South Building, Washington, DC 20250-2255.

FOR FURTHER INFORMATION CONTACT: Dr. Richard Derksen, Deputy Director, Office of the Chief Scientist, 1400 Independence Avenue SW, Room 6020, South Building, Washington, DC 20250-2255; email: rich.derksen@usda.gov. NAREEE Advisory Board website: <https://nareeeab.ree.usda.gov/>

SUPPLEMENTARY INFORMATION: All Board members serve without compensation, but may be allowed reimbursement for travel expenses, including per diem, authorized by 5 U.S.C. 5703 of the Federal Travel Regulation for persons employed intermittently in government service to attend meetings or conduct board-related business away from their homes or regular places of business.

Applications: Please note, individuals may not serve on more than one USDA Federal Advisory Committee. Individuals who are federally registered lobbyists, appointed to committees to exercise their own individual best judgment on behalf of the government (e.g., as Special Government Employees), are ineligible to serve.

Applications from individuals from across the agricultural sector—including scientists, educators, producers, interest group advocates, and other industry experts, are welcome to self-nominate and apply for a vacant position on the Advisory Board. Applications for membership to the CDS should

represent stakeholders and have knowledge of citrus industry opportunities and barriers, especially citrus diseases. All applicants will be carefully reviewed for their relevant experience, expertise, and leadership. Appointed members will serve one-, two-, or three-year terms to properly stagger term rotation. All applicants will be vetted before selection.

Instructions: To apply, submit the following: a resume/curriculum vitae (CV) (required); form AD-755 (required), a cover letter (optional); and letters of recommendation (optional). Resumes/CVs should be no longer than five (5) pages and should include the following information: the position for which you are applying; current and past organization affiliations; areas of expertise; education; career positions held; and any other notable, relevant positions held. Previous applicants/members who wish to be considered must reapply. The application may be found on the USDA website: <https://www.usda.gov/sites/default/files/documents/ad-755-advisory-committee-commodity-board-background-information.pdf>.

Applicant Selection: Appointments to the NAREEE Advisory Board and its committees and subcommittees will be made by the Secretary of Agriculture. The selection is based on how well the applicants meet the required qualifications and the current needs of the Board and its committees/subcommittees. It is anticipated that the members will start serving on the Advisory Board and/or the subcommittee in Fiscal Year 2027.

USDA will consider Committee Membership appointments, to the extent practicable and consistent with applicable laws, to ensure the needs of all Americans are served.

Equal opportunity practices in accordance with USDA's policies will be followed in all appointments to the Committee. USDA is an equal opportunity provider, employer, and lender.

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the State or local Agency that administers the program or contact USDA through the Telecommunications Relay Service at 711 (voice and TTY). Additionally, program information may be made available in languages other than English.

Dated: October 23, 2026.

Egypt Simon,

Acting USDA Committee Management Officer.

[FR Doc. 2026–21947 Filed 10–27–26; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

[Docket ID: FSA–2026–0529]

Information Collection Request; Transfer of Farm Records Between Counties

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on the revision of the following currently approved information collection request: Transfer of Records between Counties (0560–0253).

DATES: We will consider comments that we receive by December 28, 2026.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments by this method: *Federal eRulemaking Portal:* Go to: www.regulations.gov and search for Docket ID FSA–2026–0529. Follow the online instructions for submitting comments.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Tyler Gilkey.

FOR FURTHER INFORMATION CONTACT:

Tyler Gilkey, 402–437–5895, tyler.gilkey@usda.gov. Individuals with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice and text telephone (TTY mode)) or dial 711 for

Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

Description of Information Collection Requests

Title: Transfer of Farm Records Between Counties.

OMB Control Number: 0560–0253.

Expiration Date: January 31, 2027.

Type of Request: Revision.

Abstract: Farm owners or operators may request a transfer of the administration of their farm records to a different FSA county office under certain circumstances, such as a change in the principal dwelling of the farm operator, a change in the operation of the land, a change that would cause the receiving administrative county office to be more accessible (for example, the construction of a new highway or relocation of the county office), or when an FSA county office closes.

Form FSA–179, Transfer of Farm Records Between Counties, is used to record requests for farm transfers. This form collects the name and address of the person making the request, the requested State and county that the records will be transferred to if the request is approved, the reason for the transfer, and the signature of the operator and all owners to document their agreement with the request.

Form FSA–179 is available to producers at the USDA e-Forms website (<https://forms.sc.egov.usda.gov/eForms/welcomeAction.do?Home>) or in person at FSA offices. All owners and the operator of the farm being transferred are required to sign form FSA–179. The information on FSA–179 is collected in a face-to-face setting with FSA county office personnel or may be completed by customers at home and submitted to FSA.

FSA is currently reviewing how customers interact with USDA as part of the “One Farmer, One File” modernization initiative (see <https://www.fsa.usda.gov/news-events/news/03-02-2026/usda-launches-one-farmer-one-file-initiative-better-support-farmers>). Through “One Farmer, One File,” USDA’s mission is to create a single, streamlined record that follows the farmer throughout the USDA system while reducing the administrative burden for farmers and making program delivery more efficient. As part of that initiative, FSA is establishing an electronic method for customer submission of requests to transfer the administration of their farm records to a different FSA county office. The responses and burden hours associated with use of this electronic method are

included in this information collection request.

The number of respondents and responses decreased by 137 while the burden hours decreased by 19 hours. The change reflects minor variations in the number of requests submitted per year since last approval. For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per response multiplied by the estimated total annual responses.

Estimated Respondent Burden: Public reporting burden for this collection of information is estimated to average 0.167 hours per response.

Type of Respondents: Farms.

Estimated Number of Respondents: 7,407.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Number of Responses: 7,407.

Estimated Total Annual Burden on Respondents: 1,237 hours.

Request for Comments

FSA is requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of FSA, including whether the information will have practical utility;

(2) Evaluate the accuracy of FSA’s estimate of burden of the collection of information including the validity of the methodology and assumptions used;

(3) Evaluate the quality, utility, and clarity of the information to be collected;

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

William Beam,

Administrator, Farm Service Agency.

[FR Doc. 2026–21972 Filed 10–27–26; 8:45 am]

BILLING CODE 3411–E2–P

DEPARTMENT OF COMMERCE**[Docket No. DOC-2026-0397]****Privacy Act of 1974; Matching Program**

AGENCY: Office of Privacy and Open Government, Office of the Secretary, Department of Commerce.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, and Office of Management and Budget (OMB) guidance on computer matching, the Department of Commerce (Commerce) is providing notice of the establishment of a new matching program. Pursuant to the Payment Integrity Information Act of 2019, Commerce is establishing a new matching program consisting of the computerized comparison of systems of records for Federal benefit programs at Commerce with the Do Not Pay (DNP) Working System, which is administered by Treasury's Bureau of the Fiscal Service. This matching program will enable the Commerce programs listed in the appendix of this notice to compare records maintained in their respective systems of records with records maintained in the DNP Working System for the purposes of identifying and preventing improper payments and conducting any related recovery activities by verifying through DNP prepayment or pre-award eligibility.

DATES: Comments must be received on or before November 27, 2026. This new matching program will be effective 30 days after publication of this notice through September 10, 2029.

ADDRESSES: Written comments on this notice may be submitted electronically through the Federal government eRulemaking portal at <http://www.regulations.gov>; docket number DOC-2026-0397. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables Commerce to make the comments available to the public. Please note that comments submitted through <https://www.regulations.gov> will be made available for viewing by the public. Comments on this proposed matching program may also be addressed to email: PrivacyAct@doc.gov.

FOR FURTHER INFORMATION CONTACT:

Nicholas Cormier, Acting Chief Privacy Officer and Director of Open Government, CPO@doc.gov, (202) 482-1190.

SUPPLEMENTARY INFORMATION: The Computer Matching and Privacy

Protection Act of 1988 (Pub. L. 100-503) amended the Privacy Act of 1974 (5 U.S.C. 552a) by establishing procedural safeguards related to agencies' use of records when performing certain types of computerized matching. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) further amended the Privacy Act regarding protections for individuals when agencies perform these functions. Additionally, the Payment Integrity Information Act of 2019 (31 U.S.C. 3351 *et seq.*) provides the head of the agency operating the DNP Working System with the authority, in consultation with the Office of Management and Budget (OMB), to waive the requirements in 5 U.S.C. 552a(o) in any case or class of cases for matching activities conducted under the DNP Initiative (31 U.S.C. 3354). Pursuant to this authority, the Secretary of the Treasury, after consulting with the OMB Director, authorized the issuance of a four-year waiver of the requirement for entering into a matching agreement under 5 U.S.C. 552a(o) for the class of matching programs that meet all of the criteria defined in OMB Memorandum M-25-32, *Preventing Improper Payments and Protecting Privacy through Do Not Pay*.

Commerce has determined that the DNP matching program described in this notice is eligible for the waiver described in OMB Memorandum M-25-32, which is effective from September 10, 2025, through September 10, 2029. For purposes of this notice, matching activities conducted between the Federal benefit programs listed in the appendix to this document and the DNP Working System constitute a single agency-wide matching program implementing DNP for Commerce's listed programs.¹

Categories of Individuals: Applicants for, or recipients of, Federal funds from those Commerce programs listed in the appendix below.

Categories of Records: Data elements that will be matched may include:

- Taxpayer Identification Number (TIN)
- Awardee/Payee Name
- Awardee/Payee Physical Address, City, State, Zip Code

¹ The statutory definition of the term "matching program" means "any computerized comparison of—(i) two or more automated systems of records or a system of records with non-Federal records" for certain enumerated purposes. 5 U.S.C. 552a(a)(8) (emphasis added). There is a separate statutory definition for "Federal benefit program." See OMB Memorandum M-25-32 at Appendix II, page 2, sec. a.3.iii.1 (recognizing that a single agency matching program may consist of multiple systems of records). Thus, this notice applies to the DNP matching program for multiple Federal benefits programs and associated systems of records within Commerce.

- Awardee/Payee Routing Number and Bank Account Number

Commerce follow-up records may include identity-verification results, supporting documentation, correspondence and notices, contest or correction information, eligibility or payment determinations, and records documenting prevention, recoupment, recovery, referral, or other disposition.

System(s) of Records: The records contained within the DNP Working System are maintained in the system of records known as Department of the Treasury, Bureau of the Fiscal Service .017—Do Not Pay Payment Verification Records (91 FR 28759). This system of records includes those databases designated to be included in the DNP Working System by the Payment Integrity Information Act of 2019 as well as other databases designated for inclusion by the Director of the Office of Management and Budget, or the designee of the Director, in consultation with executive agencies. The Commerce records involved in the matching program are maintained in Commerce systems of records listed in the appendix below.

Appendix

Below is a list of the Commerce programs that will match records with the DNP Working System, and the applicable system of records notice(s) for each Commerce program. For purposes of this notice, matching activities conducted between the Federal benefit programs listed in the following appendix and the DNP Working System constitute a single agency-wide matching program implementing DNP for the agency.

Participating Agencies: The Commerce programs listed in the appendix of this notice will match against the DNP Working System, which is maintained by the Bureau of the Fiscal Service at the U.S. Department of the Treasury.

Authority for Conducting the Matching Program: The Payment Integrity Information Act of 2019 (31 U.S.C. 3351 *et seq.*) establishes the DNP Initiative and requires, for the purposes of identifying and preventing improper payments, each executive agency to have access to, and use of, the relevant databases in DNP to verify payment or award eligibility. Additional applicable authorities for this matching program include Executive Order 13520, *Reducing Improper Payments* (74 FR 62201); Executive Order 14249, *Protecting America's Bank Account Against Fraud, Waste, and Abuse* (90 FR 14011); and OMB Memorandum M-25-32, *Preventing Improper Payments and Protecting Privacy Through Do Not Pay*. Additional information regarding the statutory authorities for the collection and maintenance of information for each of the Commerce programs that will conduct matches with the DNP Working System are contained within the systems of records notices listed in the appendix below.

Purpose(s): The purposes of the matching program are identifying and preventing improper payments and conducting any related recovery activities by verifying through Do Not Pay prepayment or pre-award eligibility. Data elements that are necessary for eligibility determinations for a relevant Commerce program that are contained in

records from Commerce systems of records will be compared with records in the DNP Working System. When there is a match between a record provided by the Commerce program and a record in the DNP Working System, the DNP Working System will provide to the submitting Commerce program notice of a potentially matching record and

will identify the database(s) that contain the potentially matching record(s). The Commerce program will then review the information to determine whether additional action is needed. If no matches are identified, the DNP Working System will provide a no match response to the submitting Commerce program.

Commerce operating unit	Agency program name	System of records notice	Federal Register citation
National Oceanic and Atmospheric Administration (NOAA).	Marine Sanctuary Program.	COMMERCE/NOAA-14, Dr. Nancy Foster Scholarship Program; Office of Education, Educational Partnership Program (EPP); Ernest F. Hollings Undergraduate Scholarship Program and National Marine Fisheries Service Recruitment, Training, and Research Program.	80 FR 55829, Sep. 17, 2015; 80 FR 65983, Oct. 28, 2015; 91 FR 2332, Jan. 20, 2026.
NOAA	Fisheries Finance Program.	COMMERCE/NOAA-21, Financial Services Division	81 FR 44593, July 8, 2016; 91 FR 2332, Jan. 20, 2026.

Nicholas J. Cormier,

Acting Chief Privacy Officer and Director of Open Government, Office of Privacy and Open Government.

[FR Doc. 2026-21916 Filed 10-27-26; 8:45 am]

BILLING CODE 3510-17-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-141-2026]

Foreign-Trade Zone (FTZ) 155, Notification of Proposed Production Activity; Kerrville Public Utility Board Public Facility Corporation; (Natural Gas Reciprocating Internal Combustion Engine Generation Power Plant); Garwood, Texas

Kerrville Public Utility Board Public Facility Corporation submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Garwood, Texas within Subzone 155F. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on October 19, 2026.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz.

The proposed finished product is a natural gas reciprocating internal combustion engine generation power plant facility.

The proposed foreign-status materials/components include: internal combustion engines for stationary

power generation (cast iron and steel); engine flywheels (steel), engine base plates (steel), and three phase synchronous alternators (steel and copper) (duty rate ranges from duty-free to 2.4%).

The request indicates that certain materials/components are subject to duties under section 232 of the Trade Expansion Act of 1962 and section 301 of the Trade Act of 1974, depending on the country of origin. The applicable section 232 and section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is December 7, 2026.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Christopher Wedderburn at Chris.Wedderburn@trade.gov.

Dated: October 22, 2026.

Juanita Chen,

Acting Executive Secretary.

[FR Doc. 2026-21928 Filed 10-27-26; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-219, C-570-218]

Van-Type Trailers and Subassemblies Thereof From the People's Republic of China: Antidumping Duty Order and Countervailing Duty Order

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

SUMMARY: Based on affirmative final determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC), Commerce is issuing antidumping duty (AD) and countervailing duty (CVD) orders on van-type trailers and subassemblies thereof (van-type trailers) from the People's Republic of China (China).

DATES: Applicable October 28, 2026.

FOR FURTHER INFORMATION CONTACT: Jacob Waddell (AD) or Christopher Doyle (CVD), AD/CVD Operations, Offices VI and IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-1369 or (202) 482-5882, respectively.

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 705(d) and 735(d) of the Tariff Act of 1930, as amended (the Act), on August 31, 2026, Commerce published its affirmative final determination of sales at less than fair value (LTFV) of van-type trailers from China,¹ and its affirmative final determination that countervailable subsidies are being provided to producers and exporters of van-type trailers from China.²

¹ See *Van-Type Trailers and Subassemblies Thereof from the People's Republic of China: Affirmative Determination of Sales at Less Than Fair Value*, 91 FR 55837 (August 31, 2026) (*LTFV Final Determination*).

² See *Van-Type Trailers and Subassemblies Thereof from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 91 FR 55840 (August 31, 2026) (*Final CVD Determination*).

On October 15, 2026, pursuant to sections 705(d) and 735(d) of the Act, the ITC notified Commerce of its final affirmative determinations that an industry in the United States is materially injured by reason of dumped imports of van-type trailers from China and subsidized imports of van-type trailers from China, within the meaning of sections 705(b)(1)(A)(i) and 735(b)(1)(A)(i) of the Act.³

Scope of the Orders

The products covered by these orders are van-type trailers from China. For a complete description of the scope of the orders, see the appendix to this notice.

AD Order

On October 15, 2026, in accordance with section 735(d) of the Act, the ITC notified Commerce of its final determination that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of imports of van-type trailers from China that are sold in the United States at LTFV.⁴ Therefore, in accordance with sections 735(c)(2) and 736 of the Act, Commerce is issuing this AD order. Because the ITC determined that imports of van-type trailers from China are materially injuring a U.S. industry,

unliquidated entries of such merchandise from China, entered or withdrawn from warehouse for consumption are subject to the assessment of antidumping duties. Therefore, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise on all relevant entries of van-type trailers from China. Antidumping duties will be assessed on unliquidated entries of van-type trailers from China entered, or withdrawn from warehouse, for consumption on or after June 15, 2026, the date of publication of the *LTFV Preliminary Determination*, but will not include entries occurring after the expiration of the provisional measures period and before the publication of the ITC’s final injury determination under section 705(b) of the Act, as further described in the “Provisional Measures—AD” section of this notice.⁵

Continuation of Suspension of Liquidation and Cash Deposits—AD

In accordance with section 736 of the Act, Commerce intends to instruct CBP

to reinstitute the suspension of liquidation on all relevant entries of van-type trailers from China, on the date of publication of the ITC’s final affirmative injury determination in the **Federal Register**. Commerce also intends to instruct CBP to require cash deposits equal to the estimated weighted-average dumping margin indicated in the table below, adjusted by the relevant subsidy offsets. Accordingly, effective on the date of publication in the **Federal Register** of the notice of the ITC’s final affirmative injury determination, CBP must require, at the same time as importers would normally deposit estimated customs duties on subject merchandise, a cash deposit equal to the rates listed in the tables below. The rate for the China-wide entity applies to all producers or exporter combinations not specifically listed, as appropriate. These instructions suspending liquidation and imposing cash deposit requirements will remain in effect until further notice.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins are as follows:

Producer/exporter	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for export subsidy offset) (percent)
China-Wide Entity	* 130.86	129.73

* This rate is based on facts available with adverse inferences.

Provisional Measures—AD

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of export of the subject merchandise request that Commerce extend the four-month period to no more than six months. In the underlying investigation, Commerce published the *LTFV Preliminary Determination* on June 15, 2026.⁶ Therefore, the four-month period beginning on the date of publication ended on October 12, 2026. Pursuant to section 737(b) of the Act, the collection of cash deposits will begin on the date of publication of the ITC’s final injury determinations.

Therefore, in accordance with section 733(d) of the Act, Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of van-type trailers from China entered, or withdrawn from warehouse, for consumption on or after October 16, 2026, the first day provisional measures were no longer in effect, until and through the day preceding the date of publication of the ITC’s final injury determination in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC’s final determination in the **Federal Register**.

CVD Order

As stated above, on October 15, 2026, the ITC notified Commerce of its final determination that an industry in the United States is materially injured within the meaning of section 705(b)(1)(A)(i) of the Act by reason of subsidized imports of van-type trailers from China.⁷ In accordance with section 705(c)(2) of the Act, Commerce is issuing this CVD order. Moreover, because the ITC determined that imports of van-type trailers from China are materially injuring a U.S. industry, unliquidated entries of subject merchandise from China, entered or withdrawn from warehouse, for consumption, are subject to the assessment of countervailing duties.

³ See ITC’s Letter, “Notification of ITC Final Determinations,” dated October 15, 2026 (ITC Notification Letter).
⁴ *Id.*

⁵ See *Van-Type Trailers and Subassemblies Thereof from the People’s Republic of China: Preliminary Affirmative Determination of Sales at*

Less Than Fair Value, 91 FR 35957 (June 15, 2026) (*LTFV Preliminary Determination*).
⁶ See *LTFV Preliminary Determination*.
⁷ See ITC Notification Letter.

Therefore, in accordance with section 706(a) of the Act, Commerce intends to direct CBP to assess, upon further instruction by Commerce, countervailing duties on relevant entries of van-type trailers from China entered, or withdrawn from warehouse, for consumption on or after June 5, 2026, the date of publication of the *CVD Preliminary Determination*,⁸ but will not include entries occurring after the expiration of the provisional measures period and before the publication of the ITC's final injury determination under section 705(b) of the Act, as further described in the "Provisional Measures—CVD" section of this notice.

Suspension of Liquidation and Cash Deposits—CVD

In accordance with section 706 of the Act, we will instruct CBP to reinstitute the suspension of liquidation on all relevant entries of van-type trailers from China, effective on the date of publication of the ITC's final affirmative injury determination in the **Federal Register**, and to assess, upon further instruction by Commerce, pursuant to section 706(a)(1) of the Act, countervailing duties on each entry of subject merchandise in an amount based on the net countervailable subsidy rates below.

Commerce also intends, pursuant to section 706(a)(1) of the Act, to instruct CBP to require cash deposit amounts equal to the amounts indicated below.

Accordingly, effective on the date of publication of the ITC's final injury determination in the **Federal Register**, CBP will require, at the same time as importers would normally deposit estimated customs duties on this merchandise, a cash deposit equal to the rates listed in the table below.⁹ The all-others rate applies to all producers or exporters not specifically listed, as appropriate.

These instructions suspending liquidation and imposing cash deposit requirements will remain in effect until further notice.

Estimated Countervailing Duty Subsidy Rates

The estimated countervailing duty subsidy rates are as follows:

Company	Subsidy rate (percent)
CIMC Baowell Industries Co., Ltd. and Qingdao CIMC Reefer Trailer Co., Ltd	* 134.75
Chusheng Vehicle Group Co., Ltd	* 134.75
CRRC Urban Traffic Co., Ltd	* 134.75
CSCTRUCK Limited	* 134.75
Henan Huayu Jujiu Vehicle Co., Ltd	* 134.75
Henan Reddin Trading Co., Ltd	* 134.75
Henan Ulike Industry Co., Ltd	* 134.75
Hubei ChuSheng Commercial Truck	* 134.75
Hubei Chusheng Vehicles Co., Ltd. Sales Office	* 134.75
Hubei Chusheng Vehicle Co., Ltd	* 134.75
Jinan Shacman Truck Co., Ltd	* 134.75
Qihang Automobile Co., Ltd	* 134.75
Qingdao Genron International Trade Co., Ltd	* 134.75
Qingdao Quest Vehicles Equipment Co., Ltd	* 134.75
Shannxi Automobile Holding Group	* 134.75
Shandong Fuyan Special Purpose Vehicles Manufacturing Co., Ltd	* 134.75
Shandong Luen Auto Co., Ltd	* 134.75
Shandong Shodailer Automobile Manufacturing Co., Ltd	* 134.75
Shandong Tengyun Special Vehicles Manufacturing Co., Ltd	* 134.75
Xiaogong Chusheng (Hubei) Special Purpose Vehicle Manufacturing Co., Ltd	* 134.75
All Others	134.75

* This rate is based on facts available with adverse inferences.

Provisional Measures—CVD

Section 703(d) of the Act states that the suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months. Commerce published the *CVD Preliminary Determination* on June 5, 2026.¹⁰ As such, the four-month period beginning on the date of the publication of the *CVD Preliminary Determination* ended on October 2, 2026.

Therefore, in accordance with section 703(d) of the Act, we will instruct CBP to terminate the suspension of liquidation and to liquidate, without

regard to countervailing duties, unliquidated entries of van-type trailers from China entered, or withdrawn from warehouse, for consumption, on or after October 3, 2026, the first day provisional measures were no longer in effect, until and through the day preceding the date of publication of the ITC's final injury determination in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's affirmative final injury determination in the **Federal Register**.

Establishment of the Annual Inquiry Service Lists

On September 20, 2021, Commerce published the *Final Rule* in the **Federal Register**.¹¹ On September 27, 2021, Commerce also published the *Procedural Guidance* in the **Federal Register**.¹² The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the

⁸ See *Van-Type Trailers and Subassemblies Thereof from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty*

Determination, 91 FR 34222 (June 5, 2026) (*CVD Preliminary Determination*).

⁹ *Id.*

¹⁰ See *CVD Preliminary Determination*.

¹¹ See *Regulations to Improve Administration and Enforcement of Antidumping and Countervailing*

Duty Laws, 86 FR 52300 (September 20, 2021) (*Final Rule*).

¹² See *Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*, 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.

In accordance with the *Procedural Guidance*, for orders published in the **Federal Register** after November 4, 2021, Commerce will create an annual inquiry service list segment in Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available at <https://access.trade.gov>, within five business days of publication of the notice of the order. Each annual inquiry service list will be saved in ACCESS, under each case number, and under a specific segment type called "AISL-Annual Inquiry Service List."¹³

Interested parties who wish to be added to the annual inquiry service list for an order must submit an entry of appearance to the annual inquiry service list segment for the order in ACCESS within 30 days after the date of publication of the order. For ease of administration, Commerce requests that law firms with more than one attorney representing interested parties in an order designate a lead attorney to be included on the annual inquiry service list. Commerce will finalize the annual inquiry service list within five business days thereafter. As mentioned in the *Procedural Guidance*,¹⁴ the new annual inquiry service list will be in place until the following year, when the Opportunity Notice for the anniversary month of the order is published.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website.

Special Instructions for Petitioner and Foreign Governments

In the *Final Rule*, Commerce stated that, "after an initial request and

placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow."¹⁵

Accordingly, as stated above, the petitioner and the Government of China (GOC) should submit their initial entries of appearance after publication of this notice in order to appear in the first annual inquiry service lists for these orders. Pursuant to 19 CFR 351.225(n)(3), the petitioner and the GOC will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioner and the GOC are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice constitutes the AD and CVD orders with respect to van-type trailers from China, pursuant to sections 706(a) and 736(a) of the Act. Interested parties can find a list of AD and CVD orders currently in effect at <https://www.trade.gov/data-visualizations/adcvd-orders-and-suspension-agreements>.

These orders are published in accordance with sections 706(a) and 736(a) of the Act and 19 CFR 351.211(b).

Dated: October 22, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Orders

The product within the scope of these orders is certain van-type trailers and subassemblies thereof, whether finished or unfinished, whether assembled or unassembled, regardless of the number of axles, for carriage of goods. Van-type trailers are typically, but not limited to, rectangular cuboid trailers with a fully enclosed cargo space consisting of a front nose (with or without a refrigeration unit), side walls (with or without doors), movable rear panels (whether roll-up doors, swing doors, or another configuration), a floor and subframe, an affixed or removable roof, a suspension and axle system, wheels and tires, brakes, a lighting and electrical system, landing gear, and coupling for towing behind a truck tractor or a connection system for training behind another van-type trailer. Covered van-type trailers are those with a gross vehicle weight rating of greater than 26,000 pounds.

Subject merchandise includes, but is not limited to, the following subassemblies:

- Van-type trailer subframes, or sections of van-type trailer frames, typically consisting of welded crossmembers and slider rails for attaching the running gear;

- Nose wall, side wall, and roof subassemblies, whether insulated or non insulated, and with or without top, bottom, or side rails;

- Rear door frame, whether for swing or roll-up doors, with or without installed doors, bumpers, bumper plates, or reinforcing plates for liftgate;

- Door assemblies, whether for rear swing doors, roll-up doors, side doors or any other configuration, with or without lockrods, handles, hinges, or hinge pins;

- Rear impact guard subassemblies, typically consisting of a fabricated horizontal structural component (such as a guard tube) and uprights for connection to the underside of the rear frame;

- Coupler assembly for connection to truck tractor's fifth wheel, typically consisting of main beams and cross members, support plates, and front nose wrap, and with or without kingpin installed;

- Running gear subassemblies or axle assemblies for connection to the subframe, which may or may not include suspension(s), wheel end components, slack adjusters, dressed axles, brake chambers, locking pins, wheels, and tires; and

- Landing gear subassemblies, typically consisting of two landing legs, a cross channel, braces, bracketing, a cross shaft, and a crank handle.

These subassemblies are within the scope of the orders, whether entered alone or with other subassemblies and whether assembled or unassembled and whether finished or unfinished. The absence of any subassembly from an otherwise finished or unfinished van-type trailer does not remove the van-type trailer from coverage.

Subject merchandise also includes components entered with (*i.e.*, on the same bill of lading as) van-type trailers and subassemblies, such as, but not limited to: hub and drum assemblies, brake assemblies (either drum or disc), bare axles, brake chambers, suspensions and suspension components, wheel end components, landing gear legs, wheels, tires, brake control systems, electrical harnesses and lighting systems, lift gate systems, tire inflation systems, or refrigeration units (with or without evaporators or fuel tanks) whether assembled or unassembled, whether as part of a kit or not, and whether or not accompanied by additional components that constitute as part of an unfinished and/or unassembled van-type trailer and subassemblies thereof that are within the scope of the orders.

Processing of finished and unfinished van-type trailers and subassemblies, such as trimming, cutting, grinding, notching, punching, drilling, painting, coating, staining, finishing, assembly, or any other processing either in the country of manufacture of the in-scope product or in a third country does not remove the product from the scope. Inclusion of other components not identified as comprising the finished or unfinished van-type trailer does not remove the product from the scope.

¹³ This segment will be combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A-000-000 that was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as "AISL-January Anniversary." Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

¹⁴ See *Procedural Guidance*, 86 FR at 53206.

¹⁵ See *Final Rule*, 86 FR at 52335.

Specifically excluded are subassemblies covered by the scope of the antidumping and countervailing duty orders on certain chassis and subassemblies thereof from the People's Republic of China. *See Certain Chassis and Subassemblies Thereof from the People's Republic of China: Antidumping Duty Order*, 86 FR 36093 (July 8, 2021) and *Certain Chassis and Subassemblies Thereof from the People's Republic of China: Countervailing Duty Order and Amended Final Affirmative Countervailing Duty Determination*, 86 FR 24844 (May 10, 2021).

The finished and unfinished van-type trailers within the scope of the orders are typically classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 8716.39.0040, 8716.39.0090 and 8716.90.5060. Imports of finished and unfinished subassemblies may also enter under HTSUS subheadings 7308.30.5050, 7308.90.9590, 7326.90.8688, 8708.29.1500, 8708.99.8180, 8716.90.5010. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of these orders is dispositive.

[FR Doc. 2026–21929 Filed 10–27–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Rescission of Antidumping and Countervailing Duty Administrative Reviews

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

SUMMARY: Based upon the timely withdrawal of all review requests, the U.S. Department of Commerce (Commerce) is rescinding the administrative reviews covering the periods of review (PORs) of the antidumping duty (AD) and countervailing duty (CVD) orders identified in the table below.

DATES: Applicable October 28, 2026.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 CFR 351.221(c)(1)(i),¹ based upon timely requests for review, Commerce initiated administrative reviews of certain companies for the PORs and the AD and CVD orders listed in the table below. All requests for these reviews have been timely withdrawn.²

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested the review withdraw their review requests within 90 days of the date of publication of the notice of initiation for the requested review. All parties withdrew their requests for the reviews listed in the table below within the 90-day deadline. No other parties requested administrative reviews of these AD/CVD orders for the PORs noted in the table. Therefore, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding, in their entirety, the administrative reviews listed in the table below.

	Period of review
AD Proceedings	
Croatia: Common Alloy Aluminum Sheet, A–891–001	4/1/2025–3/31/2026
France: Certain Carbon and Alloy Steel Cut-To-Length Plate, A–427–828	5/1/2025–4/30/2026
Malaysia: Mattresses, A–557–818	5/1/2025–4/30/2026
Mexico: Brass Rod, A–201–858	6/1/2025–5/31/2026
Republic of Türkiye:	
Diethyl Terephthalate, A–489–852	11/5/2024–4/30/2026
Mattresses, A–489–841	5/1/2025–4/30/2026
Serbia: Common Alloy Aluminum Sheet, A–801–001	4/1/2025–3/31/2026
Slovenia: Common Alloy Aluminum Sheet, A–856–001	4/1/2025–3/31/2026
Socialist Republic of Vietnam:	
Certain Paper Plates, A–552–839	9/5/2024–2/28/2026
Mattresses, A–552–827	5/1/2025–4/30/2026
Thailand:	
Mattresses, A–549–841	5/1/2025–4/30/2026
Prestressed Concrete Steel Wire Strand, A–549–820 ³	1/1/2025–12/31/2025
The People's Republic of China: Vanillin, A–570–172	1/16/2025–6/30/2026
CVD Proceedings	
India:	
Carbazole Violet Pigment 23, C–533–839	1/1/2024–12/31/2024
Certain Non-Refillable Steel Cylinders, C–533–913	1/1/2025–12/31/2025
High Chrome Cast Iron Grinding Media, C–533–931	10/4/2024–12/31/2025
Morocco: Phosphate Fertilizers, C–714–001	1/1/2025–12/31/2025
Socialist Republic of Vietnam: Certain Paper Plates, C–552–840	7/1/2024–12/31/2025
The People's Republic of China:	
Certain Chassis and Subassemblies Thereof, C–570–136	1/1/2025–12/31/2025
Mattresses, C–570–128	1/1/2025–12/31/2025
Stainless Steel Flanges, C–570–065	1/1/2025–12/31/2025
The Russian Federation: Phosphate Fertilizers, C–821–825	1/1/2025–12/31/2025

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 91 FR 23941 (May 4, 2026); *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 91 FR 32928 (June 2, 2026); *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 91 FR

42410 (July 9, 2026); *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 91 FR 61436 (August 10, 2026); and *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 91 FR 56836 (September 4, 2026).

² The letters withdrawing the review requests may be found in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping and/or countervailing duties on all appropriate entries during the PORs noted above for each of the listed administrative reviews at rates equal to the cash deposit of estimated antidumping or countervailing duties, as applicable, required at the time of entry, or withdrawal of merchandise from warehouse, for consumption, in accordance with 19 CFR

351.212(c)(1)(i). Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this rescission notice in the **Federal Register** for rescinded administrative reviews of AD/CVD orders on countries other than Canada and Mexico. For rescinded administrative reviews of AD/CVD orders on Canada or Mexico, Commerce intends to issue assessment instructions to CBP no earlier than 41 days after the date of publication of this rescission notice in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Notification to Importers

This notice serves as the only reminder to importers of merchandise subject to AD orders of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties and/or countervailing duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in the presumption that reimbursement of antidumping duties and/or countervailing duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order (APO)

This notice also serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in these segments of these proceedings. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply

with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: October 26, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–21977 Filed 10–27–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–831]

Seamless Refined Copper Pipe and Tube From the Socialist Republic of Vietnam: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

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

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on seamless refined copper pipe and tube (copper pipe and tube) from the Socialist Republic of Vietnam (Vietnam) would be likely to lead to continuation or recurrence of dumping, at the levels indicated in the “Final Results of Sunset Review” section of this notice.

DATES: Applicable October 28, 2026.

FOR FURTHER INFORMATION CONTACT: Catherine Bonilla, Trade Agreements Policy and Negotiations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–7955.

SUPPLEMENTARY INFORMATION:

Background

On August 13, 2021, Commerce published the *Order* in the **Federal Register**.¹ On July 2, 2026, Commerce published the notice of initiation of this first sunset review of the *Order*, pursuant to section 751(c) of the Tariff Act of 1930 (the Act).² On July 9, 2026, Commerce received a timely and

complete notice of intent to participate in the sunset review for domestic interested parties within the deadline specified in the 19 CFR 351.218(d)(1)(i).³ The domestic interested party claimed the interested party status within the meaning of section 771(9)(E) of the Act as a trade or business association a majority of whose members manufacture, produce, or wholesale a domestic like product in the United States; each of its individual members is a domestic producer and an interested party under section 771(9)(C) of the Act.⁴ On July 30, 2026, Commerce notified the U.S. International Trade Commission (ITC) that it had received a notice of intent to participate from the domestic interested parties.⁵

On July 22, 2026, pursuant to 19 CFR 351.218(d)(3)(i), domestic interested parties filed a timely and adequate substantive response.⁶ Commerce did not receive a substantive response from any respondent interested party. On August 24, 2026, Commerce notified the ITC that it did not receive substantive response from any respondent interested parties.⁷ As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce is conducting an expedited (120-day) sunset review of the *Order*.

Scope of the Order

The product covered by this *Order* is copper pipe and tube from Vietnam. For the full description of the scope of the *Order*, see the Issues and Decisions Memorandum.⁸

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *Order* and the magnitude of the margins likely to prevail if the *Order* were to be revoked, is provided in the accompanying Issues and Decision Memorandum.⁹ A list of the topics discussed in the Issues and

³ See Domestic Interested Party’s Letter, “Notice of Intent to Participate,” dated July 9, 2026.

⁴ *Id.* at 2.

⁵ See Commerce’s Letter, “Sunset Reviews Initiated on July 2, 2026,” dated July 30, 2026.

⁶ See Domestic Interested Party’s Letter, “Substantive Response of the Coalition and its Members to Commerce’s Notice of Initiation,” dated July 22, 2026.

⁷ See Commerce’s Letter, “Sunset Reviews Initiated on July 2, 2026,” dated August 24, 2026.

⁸ See Memorandum, “Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Antidumping Duty Order on Seamless Refined Copper Pipe and Tube from the Socialist Republic of Vietnam,” dated concurrently with, and hereby adopted by, this notice.

⁹ *Id.*

³ In the rescission of antidumping and countervailing duty administrative reviews notice that published on August 11, 2026 (91 FR 51664), Commerce inadvertently listed the wrong period of review for the case above, the correct period of review is listed. This serves as a correction.

¹ See *Seamless Refined Copper Pipe and Tube from the Socialist Republic of Vietnam: Antidumping Duty Order*, 86 FR 44691 (August 13, 2021) (*Order*).

² See *Initiation of Five-Year (Sunset) Reviews*, 91 FR 40515 (July 2, 2026).

Decision Memorandum is attached in the Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be directly accessed at <https://access.trade.gov/frnotices>.

Final Results of Sunset Review

Pursuant to sections 751(c)(1), 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Order* would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 8.35 percent for copper pipe and tube from Vietnam.

Notification Regarding Administrative Protective Orders

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials, or conversion to judicial protective, orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218 and 19 CFR 351.221(c)(5)(ii).

Dated: October 22, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. History of the Order
- V. Legal Framework
- VI. Discussion of the Issues
 1. Likelihood of Continuation or Recurrence of Dumping
 2. Magnitude of the Margins of Dumping Likely to Prevail
- VII. Final Results of Sunset Review

VIII. Recommendation

[FR Doc. 2026–21930 Filed 10–27–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XG125]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Mackerel, Squid, and Butterfish Monitoring Committee will hold a public meeting.

DATES: The meeting will be held on Tuesday, November 17, 2026, from 9 a.m. to 12 p.m. ET. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar. Connection information will be posted to the Council's calendar prior to the meeting at <https://www.mafmc.org>.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; <https://www.mafmc.org>.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fishery Management Council's Mackerel, Squid, and Butterfish Monitoring Committee will meet via webinar on Tuesday, November 17, 2026, from 9 a.m. until 12 p.m. (Eastern time). The main purpose of the meeting is for the Monitoring Committee to review fishery performance and the catch recommendations of the Scientific and Statistical Committee, and then to provide recommendations to the Council on appropriate specifications and associated fishing measures for Longfin squid. The butterfish discard cap will also be discussed. The roles of Monitoring Committees are detailed here: https://www.mafmc.org/s/MC-role-summary-updated_2026-05-11.pdf.

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shelley Spedden, (302) 526–5251 at least 5 days prior to the meeting date.

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

Dated: October 26, 2026.

Anna Michelle Harrison,

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

[FR Doc. 2026–21988 Filed 10–27–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XG110]

Fisheries of the Caribbean, Gulf of America, and South Atlantic; Reef Fish Fishery of the Gulf and Coastal Migratory Pelagic Fishery of the Gulf and Atlantic Region; Request for an Exempted Fishing Permit

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

ACTION: Notice of receipt of an application for an exempted fishing permit; request for comments.

SUMMARY: NMFS announces the receipt of an application for an exempted fishing permit (EFP) to support cooperative research activities funded by the NOAA RESTORE Science Program to verify, characterize, monitor, and model multi-species fish spawning aggregations in Federal waters of the Gulf of America (Gulf). This notice gives the public an opportunity to review the application and provide comments to NMFS regarding the request for an EFP.

DATES: Written comments must be received no later than November 12, 2026.

ADDRESSES: You may submit comments on the application, identified by NOAA–NMFS–2026–2806, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and type NOAA–NMFS–2026–2806 in the Search box. Click the “Comment” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit all written public comments to Frank Helies, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public

viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments. Enter “N/A” in the required fields if you wish to remain anonymous.

An electronic copy of the application may be obtained from the Southeast Regional Office website at <https://www.fisheries.noaa.gov/southeast/sustainable-fisheries/cooperative-research-and-management-fish-spawning-aggregations-gulf/>.

FOR FURTHER INFORMATION CONTACT:

Frank Helies, phone: 727–824–5305, email: frank.helies@noaa.gov.

SUPPLEMENTARY INFORMATION: The EFP is requested under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

NMFS received a request from Sustainable Marine Solutions to obtain an EFP that would exempt research activities funded by the NOAA RESTORE Science Program. The goals of the research are to verify, characterize, monitor, and model multi-species fish spawning aggregations (FSAs) in Federal waters of the Gulf. The applicant requested exemptions from the applicable Federal regulations for project participants to harvest several species of Gulf reef fish and coastal migratory pelagic anytime during a year. If NMFS issues the EFP, the EFP could exempt participants from bag and size limits and area and seasonal closures. The applicant requested that the EFP be valid through December 31, 2030. The EFP request is further summarized below. Specific details, explanations, and reference citations are available in the submitted application (see **ADDRESSES**).

The proposed project would engage federally permitted commercial and recreational charter vessel (for-hire) fishermen to bridge the science-to-policy gap via advisory groups and an inclusive process to identify priority FSAs for characterization, monitoring, and modeling. The would conduct cooperative research trained professional captains on up to 120 sampling trips over 4 years (approximately 30 trips per year). An initial set of sites was identified during a workshop funded by the RESTORE Science Program and additional sites would be identified during meetings

with small groups of fishermen during 2026 and 2027 and opportunistically through the life of project using information from a large monitoring database, bathymetric data, and geomorphological and seasonal cues from published and grey literature reports, as well as fishermen’s knowledge. The applicant would prioritize those potential FSA sites for verification sampling using criteria developed in collaboration with scientists, managers, and fishermen.

FSAs can be verified using direct evidence (e.g., observed gamete release or gonad dissection) and supported by indirect evidence (e.g., courtship coloration and behavior). The EFP would allow the trained captains to attempt to verify FSAs. Fishermen would conduct limited sampling to verify predicted spawning aggregations largely following protocols outlined in Heyman *et al.* (2017). To ensure data quality, accountability, and project management, captains would undergo training and certification by RESTORE project partners to participate as members of a Study Fleet. Study Fleet participants would operate federally-permitted commercial or recreational for-hire fishing vessels. Participants would be compensated through pre-agreed arrangements.

Sampling trips would be authorized for pre-agreed and limited numbers of pre-determined species at highly specific, pre-agreed times and locations. Target species would include commercially and recreationally important species that are known to aggregate to spawn, including federally-managed triggerfish, groupers, snappers, jacks, mackerel, and cobia. The number of annual samples to be collected at each predicted time and location would be minimal (between 2–5 fish), particularly for large-bodied and slower growing species. In total, the EFP requests permission to collect 233 fishes each year for four years. (See table 1 in the application for details.) Potential study sites include the entire Gulf in depths from 10 to 1,800 feet (1 foot is approximately 0.305 meters) and sampling may occur at any time of the year.

Prior to each sampling trip, Study Fleet participants would complete a pre-trip agreement form with RESTORE scientists and be provided with all necessary equipment for sample and data collection. At specified times and locations, Study Fleet participants would use hook-and-line gear (automatic reel, bandit gear, bottom longline, and rod and reel) to capture targeted species. When captured, each sampled fish would be marked with an

identifying tag and photographed to mark time and location of sampling. These samples would be immediately immersed in an ice bath for rapid cooling and euthanasia and then stored on ice. Samples would be returned to the dock as soon as practicable, but no more than 48 hours post capture to ensure sample quality. Study Fleet participants would coordinate their return with RESTORE project partners, who would serve as dockside samplers. Samplers, pre-trained and certified for data collection in this project, would meet Study Fleet participants upon their arrival. Study Fleet collected samples and associated data sheets would be transferred to project scientists and recorded with chain of custody signatures to ensure all samples are accounted for, sample numbers do not exceed agreed-upon numbers or species, and serve as documentation to support fishermen’s compensation.

Non-target species caught during sampling would be noted on the data sheet. These fishes would either be released, with a descending device if possible, or retained by Study Fleet participants if retention is permitted under the applicable regulations. All other fishes collected for the study would be donated to charity.

Project scientists would append the field data sheet to include measurements recorded at dockside. These would include time and location of capture, species, sex, morphometrics, and photographs of the entire fish with gonads extracted and close-up photographs of gonads only. Otoliths would be removed for aging and gonad samples would be collected for histology to determine sex and reproductive status as in Brown-Peterson *et al.* (2011). Aging and histological analysis would be conducted under contract with the Marine Resources Monitoring, Assessment and Prediction program, otherwise referred to as MARMAP. NMFS finds the application warrants further consideration based on a preliminary review. In order to allow Study Fleet participants to conduct the requested sampling using commercial and for-hire vessels throughout the Gulf during any time of year, the EFP may include exemptions from size limits specified in 50 CFR 622.37 and 622.380, bag limits specified in 50 CFR 622.38 and 622.382, individual fishing quota requirements specified in 50 CFR 622.21 and 622.22, seasonal and area closures specified in 50 CFR 622.34 and 622.36, and restrictions on sale and purchase specified in 50 CFR 622.40 and 622.386. Possible conditions the agency may impose on the permit, if granted,

include but are not limited to, a prohibition on sampling within marine protected areas, marine sanctuaries, special management zones, or areas where testing might interfere with managed fisheries without additional authorization. Additionally, NMFS may require special protections for Endangered Species Act-listed species and designated critical habitat and may require particular gear markings. A final decision on issuance of the EFP will depend on NMFS' review of public comments received on the application, consultations with the appropriate fishery management agencies of the affected states, the Gulf Fishery Management Council, and the U.S. Coast Guard, and a determination that the activities to be taken under the EFP are consistent with all applicable laws.

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

Dated: October 26, 2026.

Shannon Bettridge,

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

[FR Doc. 2026-21999 Filed 10-27-26; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth a new schedule and proposed agenda for a meeting of the NOAA Science Advisory Board (SAB) that will take place on November 17–18, 2026. During this meeting members will discuss issues outlined in the section on Matters to be Considered.

DATES: The meeting is scheduled for November 17–18, 2026, from 10:00 a.m. Eastern Time to 5:00 p.m. Eastern Time. The time and the agenda topics described below are subject to change. For the latest agenda please refer to the SAB website: <https://sab.noaa.gov/current-meetings/>.

ADDRESSES: The November 17–18, 2026 meeting will take place at AGU Conference Center, 2000 Florida Avenue NW, Washington, DC 20009; Phone Number: 240-381-0833; Email: noaa.scienceadvisoryboard@noaa.gov. The link for the meeting will be posted, when available, on the SAB website: <https://sab.noaa.gov/current-meetings/>.

FOR FURTHER INFORMATION CONTACT: Casey Stewart, Executive Director,

SSMC3, Room 11360, 1315 East-West Hwy., Silver Spring, MD 20910; Phone Number: 240-381-0833; Email: noaa.scienceadvisoryboard@noaa.gov; or visit the SAB website at <https://sab.noaa.gov/current-meetings/>.

SUPPLEMENTARY INFORMATION: NOAA's Science Advisory Board (SAB) was originally established by a Decision Memorandum dated September 25, 1997. In 2017, the SAB became a non-discretionary committee when Congress mandated that the SAB shall continue to maintain two specific subcommittees [Weather Research and Forecasting Innovation Act of 2017 (Pub. L. 115-25) 401, 508]. The SAB is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on long- and short-range strategies for research, education, and the application of science to resource management and environmental assessment and prediction. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Status: The November 17–18, 2026 meeting will be open to public participation with a 20-minute public comment period at the time allocated on the published agenda. Public statements presented at the meeting should not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of three minutes. Written comments for the November 17–18, 2026 meeting should be received by the SAB Executive Director's Office (noaa.scienceadvisoryboard@noaa.gov) by November 10, 2026, to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after this date will be distributed to the SAB, but may not be reviewed prior to the meeting date.

Special Accommodations: This meeting is accessible to people with disabilities. Requests for special accommodations may be directed to the SAB Executive Director no later than 12:00 p.m. EDT on November 10, 2026.

Matters to be Considered: The meeting on November 17–18, 2026 will include the following topic(s): (1) A consent calendar for approval of the June 4th Minutes and membership updates, (2) NOAA Update by the NOAA Under Secretary, (3) SAB Work Plan, (4) NOAA Scientific Priority Tiger Team Updates and, (5) NOAA response presentations to SAB reports.

Meeting materials, including work products, will also be available on the SAB website: <https://sab.noaa.gov/current-meetings/>.

Nikola M. Garber,

Deputy Director, National Sea Grant College Program, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2026-21952 Filed 10-27-26; 8:45 am]

BILLING CODE 3510-KD-P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Monday, November 10, 2026—11:00 a.m.

PLACE: The meeting will be held remotely.

STATUS: Closed Commission Meeting.

MATTER TO BE CONSIDERED: Briefing matter.

CONTACT PERSON FOR MORE INFORMATION:

Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 441 G Street NW, Washington, DC 20548, 301-504-7479 (Office) or 240-863-8938 (Cell).

Dated: October 26, 2026.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2026-21980 Filed 10-26-26; 4:15 pm]

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Monday, November 2, 2026—1:00 p.m.

PLACE: The meeting will be held remotely.

STATUS: Closed Commission Meeting.

MATTER TO BE CONSIDERED: Briefing matter.

CONTACT PERSON FOR MORE INFORMATION:

Alberta E. Mills, Office of the Secretary, U.S. Consumer Product Safety Commission, 441 G Street NW, Washington, DC 20548, 301-504-7479 (Office) or 240-863-8938 (Cell).

Dated: October 26, 2026.

Alberta E. Mills,

Commission Secretary.

[FR Doc. 2026-21968 Filed 10-26-26; 11:15 am]

BILLING CODE 6355-01-P

DEPARTMENT OF DEFENSE**Department of the Air Force****Notice of Intent To Prepare an Environmental Impact Statement for Training and Exercises at Airfields in the Commonwealth of the Northern Mariana Islands**

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: The Department of the Air Force (DAF) is issuing this Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) to assess the potential social, economic, and environmental effects associated with conducting aircraft training and exercises at airfields in the Commonwealth of the Northern Mariana Islands (CNMI), including Saipan International Airport, Tinian International Airport, Tinian North Field, and Rota International Airport. DAF is the lead agency for the CNMI Airfields Training and Exercises (CATE) EIS and intends to invite the Federal Aviation Administration and Commonwealth Ports Authority to be cooperating agencies. DAF will consult with, and obtain the comments of, federal agencies that have jurisdiction by law or special expertise related to the environmental analysis.

DATES: A public scoping period of 30 days will take place starting from the date of this NOI publication in the **Federal Register**. DAF requests comments on alternatives, impacts, relevant information, studies, or analyses with respect to the Proposed Action. Comments should be submitted in writing to the website or address listed in the **ADDRESSES** section and will be accepted at any time during the EIS process; however, to ensure the DAF has sufficient time to consider public input, please submit within the 30-day scoping period. The Draft EIS is anticipated in Fall 2027 and the Final EIS is anticipated in Summer 2028.

DAF invites the public, stakeholders, and other interested parties to attend the public scoping meetings to be held on the following dates and times.

- November 18, 2026, 5:00 p.m. to 8:00 p.m., ChST, Saipan
- November 19, 2026, 5:00 p.m. to 8:00 p.m., ChST—, Tinian
- November 21, 2026, 12:00 p.m. to 3:00 p.m., ChST, Rota

Information that will be provided at the public scoping meetings is available on the project website (www.CATEEIS.com). Attendees of the public scoping meetings will have the

opportunity to submit written comments.

ADDRESSES: The Saipan meeting will be held at Pacific Islands Club, San Antonio, Saipan. The Tinian meeting will be held at Tinian Western Lodge, Marpo Heights, Tinian. The Rota meeting will be held at the Rota Mayor's Office, Tatachok, Rota with potential alternate locations for Rota being the Courthouse or Round House. Addresses for the in-person public scoping meetings listed in the **DATES** section will be published in local newspaper and on the project website a minimum of 15 days prior to the meetings. Written scoping comments can be submitted at an in-person scoping meeting or via the project website www.CATEEIS.com. Scoping comments may also be submitted by email to PACAF.NEPA.CATEEIS@us.af.mil, or by mail to AFIMSC Det 2/CEV, ATTN: CATE EIS, 25 E ST STE C-310, JBPHH, HI 96853.

FOR FURTHER INFORMATION CONTACT: For inquiries regarding accommodations under the Americans with Disabilities Act or questions regarding the Proposed Action, scoping, and EIS development please contact Shawn Williams at PACAF.NEPA.CATEEIS@us.af.mil or by phone at 1 (808) 789-7446.

SUPPLEMENTARY INFORMATION: The purpose of the Proposed Action is to conduct aircraft training and exercises at operable airfields in the CNMI to enhance DAF operational readiness and resiliency by conducting distributed operations across multiple locations within a single U.S. territory. The Proposed Action would enable DAF to test and employ tailorable force packages; exercise movement, sustainment, logistics, and command-and-control functions across multiple locations to replicate the complexity of distributed operations in contingency environments; and strengthen interoperability with joint, allied, and partner forces within the Mariana Islands region. The Proposed Action is needed to improve DAF's ability to conduct distributed operations across multiple locations in a compressed U.S. geographic area in support of the Agile Combat Employment concept and to maintain operational readiness and responsiveness in the Indo-Pacific. DAF requires opportunities to train and exercise personnel, aircraft, and equipment across multiple locations in the CNMI to develop the skills, procedures, and relationships necessary to rapidly maneuver, sustain, and employ forces in a dynamic operational environment. The proposal is based on DAF requirements but could also

support training and exercises involving other Department of Defense services, allies, or partner nations.

The EIS will assess the potential environmental consequences of the Proposed Action, which includes conducting small, medium, and large training and exercise events at CNMI airfields, consisting of up to 1,200 fixed-wing and 320 rotary-wing operations (e.g., takeoffs and landings) per airfield annually. Training and exercise events would be supported by up to 550,000 gallons of fuel per airfield, including fuel receipt, storage and distribution; up to 1,000 personnel per airfield; temporary installation of expeditionary infrastructure and utilities; munitions handling including chaff and flare; support services; and associated pre-and post-training and exercise activities. The Proposed Action does not include construction, creation or modification of airspace, or an increase or change in munitions expenditures beyond those analyzed in previous NEPA documentation. The EIS will also consider Alternative 1 to the Proposed Action, which consists of conducting aircraft operations at an intensity 20 percent greater than the Proposed Action (i.e., up to 1,400 fixed-wing operations and up to 384 rotary-wing operations per airfield annually), and the No Action Alternative.

DAF will pursue all required permits, licenses, and other authorizations for the project including, but not limited to consultations under Section 7 of the Endangered Species Act, Section 106 of the National Historic Preservation Act, coastal zone consistency under the Coastal Zone Management Act, and Clean Air Act compliance.

(Authority: 42 United States Code 4321, *et seq.*, and Department of War and Department of Air Force National Environmental Policy Act Implementing Procedures.)

Crystle C. Poge,

Air Force Federal Register Liaison Officer.

[FR Doc. 2026-21969 Filed 10-27-26; 8:45 am]

BILLING CODE 3911-44-P

DEPARTMENT OF DEFENSE**Department of the Army****Notice of Termination of Environmental Impact Statement for the Orange and Rockland Utilities Transmission Line Upgrade Project, West Point, New York**

AGENCY: Department of the Army, DoD.

ACTION: Notice of termination.

SUMMARY: The Department of the Army (Army) is terminating the preparation of

an EIS addressing the Orange and Rockland Utilities Transmission Line Upgrade project at West Point, New York.

DATES: This termination is effective on the date of this notice.

FOR FURTHER INFORMATION CONTACT: Dr. David Guldenzopf, Director for Environmental Compliance and Mission Readiness, Office of the Assistant Secretary of the Army for Installations, Energy and Environment, at (703) 459-7756, david.b.guldenzopf.civ@army.mil.

SUPPLEMENTARY INFORMATION: The Department of the Army hereby provides notice of termination of the subject EIS, which was initiated by a Notice of Intent to Prepare an Environmental Impact Statement. The Notice of Intent was published in the **Federal Register** on 15 July 2022 (87 FR 42448). The EIS concerned potential environmental impacts associated with real estate transactions and a related utilities infrastructure upgrade at West Point, NY. Accordingly, the EIS initiated on July 15, 2022, is hereby terminated.

Authority: National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*; Department of War NEPA Implementing Procedures, April 30, 2026.

James W. Satterwhite, Jr.,
Army Federal Register Liaison Officer.

[FR Doc. 2026-22004 Filed 10-27-26; 8:45 am]

BILLING CODE 3711-CC-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2026-OS-2344]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Intelligence and Security (OUSD(I&S)) Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Defense Counterintelligence and Security Agency (DCSA) announces a 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 28, 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 Defense, 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 instruments, please write to DCSA, 27130 Telegraph Rd., Quantico, VA 22134, Nicholas Daly, 667-424-3558.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Standard Form (SF) 87 Fingerprint Charts; SF 87; OMB Control Number 0705-0002.

Needs and Uses: The SF 87 fingerprint card is utilized to conduct a national criminal history check, which is a component of a background investigation. The SF 87 is completed by applicants who are under consideration for Federal employment; by Federal employees, to determine whether they should be retained in such employment; by individuals being considered to perform work for the Federal Government under a Government contract or to continue such work; and by persons seeking long-term access to Federal facilities and systems. The SF 87 fingerprint chart is used in background investigations to help establish facts required to determine, for example, whether the subject of the investigation should be adjudicated to be eligible for logical and

physical access to Government facilities and systems; suitable or fit for Federal employment; fit to perform work on behalf of the Federal Government under a Government contract; eligible to hold a position that is sensitive for national security reasons; or eligible for access to classified information. The SF 87 form is utilized only when a hardcopy fingerprint chart must be obtained, as opposed to the electronic collection of fingerprints.

Affected Public: Individuals or households.

Annual Burden Hours: 3,458.

Number of Respondents: 41,500.

Responses per Respondent: 1.

Annual Responses: 41,500.

Average Burden per Response: 5 minutes.

Frequency: As required.

Dated: October 23, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026-21938 Filed 10-27-26; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN-2026-HQ-0529]

Proposed Collection; Comment Request

AGENCY: Department of the Navy, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Naval Air Warfare Center Aircraft Division announces the proposed extension of an approved public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the 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 28, 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 Defense, 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 instruments, please write to Naval Air Warfare Center Aircraft Division, 22347 Cedar Point Road, Building 2185, Patuxent River, MD 20670; ATTN: Ms. Crystal Krater, or call 240-717-6777.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: NAWCAD STEM Education Outreach Programs; NAWCAD Forms 5726/1, 5726/2, and 5726/4; OMB Control Number 0703-0096.

Needs and Uses: The mission of the Naval Air Warfare Center Aircraft Division's (NAWCAD) Strategic Education Office (SEO) is to provide meaningful opportunities for students in the areas of Science, Technology, Engineering, and Mathematics (STEM) through outreach activities to middle school and high school students. The purpose of the STEM programs is to provide interactive learning experiences for middle school and high school students to create awareness of the additional internship opportunities and naval careers encouraging students to pursue STEM education and career fields. Through the Southern Maryland region partnership agreements between federal agencies and educational institutions providing support and services to public and private school students, the NAWCAD SEO assists in orchestrating of variety of engagement activities to include NAWCAD hosted annual STEM centric summer camp programs, classroom speaking and demonstrations, school field trips, mentorships, and the organizing of volunteer support for all activities. To

facilitate annual events, information must be collected from local area educational institutions, community groups, and/or students via three forms: NAWCAD 5726/1, "NAWCAD SEO Program Request," NAWCAD 5726/2, "NAWCAD SEO Science Fair Mentor Program Student Application," and NAWCAD 5726/4, "NAWCAD SEO Program Registration."

Affected Public: Individuals or households; State, Local or Tribal Government.

NAWCAD SEO Program Request

Annual Burden Hours: 15.
Number of Respondents: 30.
Responses per Respondent: 1.
Annual Responses: 30.
Average Burden per Response: 30 minutes.

NAWCAD SEO Science Fair Mentor Program Student Application

Annual Burden Hours: 9.
Number of Respondents: 18.
Responses per Respondent: 1.
Annual Responses: 18.
Average Burden per Response: 30 minutes.

NAWCAD SEO Program Registration

Annual Burden Hours: 29.
Number of Respondents: 87.
Responses per Respondent: 1.
Annual Responses: 87.
Average Burden per Response: 20 minutes.

Total Burden

Annual Burden Hours: 53.
Number of Respondents: 135.
Annual Responses: 135.
Frequency: On occasion.

Dated: October 23, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026-21937 Filed 10-27-26; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN-2026-HQ-0365]

Submission for OMB Review; Comment Request

AGENCY: Department of the Navy, 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 27, 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:

Reginald Lucas, (571) 372-7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Navy CHINFO Quarterly Brand Opinion Survey; OMB Control Number 0703-0090.

Type of Request: Revision.

Number of Respondents: 16,000.

Responses per Respondent: 1.

Annual Responses: 16,000 (4,000 quarterly).

Average Burden per Response: 15 minutes.

Annual Burden Hours: 4,000.

Needs and Uses: The Navy Chief of Information (CHINFO) requires this recurrent information collection to fulfill its mandate under Office of the Chief of Naval Operations (OPNAV) Instruction 5726.8C, "Outreach: America's Navy," which requires providing public affairs advice to the Secretary of the Navy and the OPNAV. To provide informed, strategic counsel, CHINFO must continuously assess the public communication environment, track public understanding of the U.S. Navy and its operations, and monitor recent trends that affect public perception. This empirical brand and opinion research is necessary to evaluate current public perceptions, advise senior U.S. Navy leadership on how emerging global issues will be received, and plan strategic communication strategies around the release of information.

CHINFO uses the quantitative data collected quarterly from representative online panels to evaluate public knowledge, favorability, capability perception, and engagement with the Navy. These insights allow CHINFO to adjust its public communication efforts, address areas of low awareness or misunderstanding, and brief senior leaders on national sentiment regarding

defense capabilities, spending, and emerging threats.

Affected Public: Individuals or households.

Frequency: Quarterly.

Respondent's Obligation: Voluntary.

DoD Clearance Officer: Mr. Reginald Lucas.

Dated: October 23, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026-21935 Filed 10-27-26; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN-2026-HQ-0364]

Submission for OMB Review; Comment Request

AGENCY: Department of the Navy, 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 27, 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: Reginald Lucas, (571) 372-7574, whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Fleet Readiness Center Southeast Contractor Access Badge Intake; OMB Control Number 0703-0089.

Type of Request: Extension.
Number of Respondents: 1,600.
Responses per Respondent: 1.
Annual Responses: 1,600.
Average Burden per Response: 7 minutes.

Annual Burden Hours: 187.

Needs and Uses: The Fleet Readiness Center Southeast (FRCSE) Contractor

Access Badge Intake collection is necessary to process access-badge requests from contractor personnel who require access to FRCSE facilities to perform official contract duties. Authorized FRCSE Security Department personnel collect standardized information during an in-person intake and enter the information into the Computer Coordinated Universal Retrieval Entry (CCURE) 9000 access-control system. The information is used to verify contractor identity and affiliation, confirm the contractor's need for access, issue and manage access badges and associated permissions, maintain badge holder accountability and emergency-contact information, and support authorized physical-security, emergency-response, and security-incident activities. Contractor personnel do not directly access or enter information into the CCURE 9000 system.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

DOD Clearance Officer: Mr. Reginald Lucas.

Dated: September 23, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026-21934 Filed 10-27-26; 8:45 am]

BILLING CODE 3810-FF-P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID: USN-2026-HQ-0530]

Proposed Collection; Comment Request

AGENCY: Department of the Navy, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Naval Intelligence Activity announces the proposed extension of an approved public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the 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 28, 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 Defense, 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 instruments, please write to Department of the Navy, Naval Intelligence Activity, 4251 Suitland Road, Washington, DC 20395, ATTN: Marion Villanova, or call 301-669-2861.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Navy Insider Threat Report Form; OPNAV 5510/423; OMB Control Number 0703-0092.

Needs and Uses: The Department of the Navy uses Office of the Chief of Naval Operations (OPNAV) Form 5510/423, Navy Insider Threat Report, to collect standardized information concerning potential insider threats in support of the Navy Insider Threat Program. The collection supports the Navy's implementation of Executive Order 13587, which requires executive branch agencies to establish insider threat programs to deter, detect, and mitigate insider threats and unauthorized disclosures of classified national security information.

The form enables the Navy Analytic Hub to receive, assess, integrate, and respond to reports of concerning behavior or other information that may indicate a potential insider threat. Use of a standardized form reduces the need for repeated follow-up communications

and provides a consistent means to document relevant information, including submitter information, available information about the subject of the report, a narrative description of the concern, and any known mitigation actions or previous reporting.

The form may be completed by individuals reporting observed incidents or information within their knowledge, as well as by Navy personnel gathering information in support of an insider threat inquiry. For purposes of the Paperwork Reduction Act, the collection accounts only for burden imposed on contractor respondents. Respondents provide only the information available to them; they are not expected to provide personal information about a report subject or information concerning mitigation measures when they do not have access to that information. Navy Analytic Hub personnel may supplement incomplete reports using authorized Government sources and coordination with appropriate command personnel.

Information collected through OPNAV Form 5510/423 is used to support the Navy Insider Threat Program's mission to prevent, detect, deter, and mitigate risks posed by malicious or unwitting insiders.

Affected Public: Individuals or households.

Annual Burden Hours: 25.

Number of Respondents: 100.

Responses per Respondent: 1.

Annual Responses: 100.

Average Burden per Response: 15 minutes.

Frequency: On Occasion.

Dated: October 23, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026-21936 Filed 10-27-26; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2026-SCC-1552]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Build America, Buy America Act (BABAA) Domestic Sourcing Requirements Waiver—United States Department of Education BABAA Waiver Request Form

AGENCY: Office of the Secretary (OS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of

1995, the Department is proposing a reinstatement without change of a previously approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before November 27, 2026.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting "Department of Education" under "Currently Under Review," then check the "Only Show ICR for Public Comment" checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the "View Information Collection (IC) List" link. Supporting statements and other supporting documentation may be found by clicking on the "View Supporting Statement and Other Documents" link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact John English, john.english@ed.gov.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Build America, Buy America Act (BABAA) Domestic Sourcing Requirements Waiver—United States Department of Education BABAA Waiver Request Form.

OMB Control Number: 1894-0018.

Type of Review: Reinstatement without change of a previously approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 47.

Total Estimated Number of Annual Burden Hours: 470.

Abstract: In accordance with section 70914 of the Build America Buy America Act (Pub. L. 117-58 §§ 70901-70953) (BABAA), grantees funded under Department of Education (the Department) programs that allow funds to be used for infrastructure projects (infrastructure programs), *i.e.*, construction and broadband infrastructure, may not use their grant funds for these infrastructure projects or activities unless they comply with the following BABAA sourcing requirements: (1) All iron and steel used in the infrastructure project or activity are produced in the United States, (2) All manufactured products used in the infrastructure project or activity are produced in the United States, and (3) All construction materials are manufactured in the United States.

The Department may, in accordance with sections 70914(b) and (d), 70921(b), 70935, and 70937 of BABAA, and the Office of Management and Budget Memorandum M 22-11, Initial Implementation Guidance on Application of Buy America Preference in Federal Financial Assistance Programs for Infrastructure, approve waivers to BABAA sourcing requirements submitted by grantees under programs it has identified as infrastructure programs when it determines that exceptions to these requirements apply. The Department may approve, subject to notice and comment requirements and the Office of Management and Budget Made in America Office (MIAO) review, the types of waivers listed below when one or more of the following conditions are met: (1) Public Interest Waiver—Applying the BABAA sourcing requirement would be inconsistent with the public interest, (2) Non-availability Waiver—The types of iron, steel, manufactured products, or construction materials are not produced in the United States in sufficient and reasonably available quantities or of a satisfactory quality, and (3) Unreasonable Cost Waiver—The inclusion of iron, steel, manufactured products, or construction materials produced in the United States will increase the cost of the overall project by more than 25 percent.

Ross Santy,

Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026-21962 Filed 10-27-26; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings #1**

Take Notice That the Commission Received the Following Electric Corporate filings:

Docket Numbers: EC27–8–000.

Applicants: Kendall Green Energy LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Kendall Green Energy LLC.

Filed Date: 10/21/26.

Accession Number: 20261021–5206.

Comment Date: 5 p.m. ET 11/12/26.

Take Notice That the Commission Received the Following Exempt Wholesale Generator filings:

Docket Numbers: EG27–17–000.

Applicants: Adams Creek Solar Project, LLC.

Description: Adams Creek Solar Project, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 10/21/26.

Accession Number: 20261021–5208.

Comment Date: 5 p.m. ET 11/12/26.

Docket Numbers: EG27–18–000.

Applicants: Tymochtee Solar, LLC.
Description: Tymochtee Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 10/22/26.

Accession Number: 20261022–5158.

Comment Date: 5 p.m. ET 11/12/26.

Docket Numbers: EG27–22–000.

Applicants: Dixon Solar, LLC.
Description: Dixon Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 10/22/26.

Accession Number: 20261022–5170.

Comment Date: 5 p.m. ET 11/12/26.

Docket Numbers: EG27–23–000.

Applicants: Shawboro East Ridge Solar, LLC.

Description: Shawboro East Ridge Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 10/22/26.

Accession Number: 20261022–5184.

Comment Date: 5 p.m. ET 11/12/26.

Take Notice That the Commission Received the Following Electric Rate filings:

Docket Numbers: ER10–1585–029; ER10–1594–029; ER10–1617–029; ER10–1628–029; ER10–1632–031; ER16–733–020.

Applicants: LQA, LLC, Tenaska Power Services Co., Texas Electric

Marketing, LLC, New Mexico Electric Marketing, LLC, California Electric Marketing, LLC, Alabama Electric Marketing, LLC.

Description: Notice of Change in Status of Alabama Electric Marketing, LLC, et al.

Filed Date: 10/21/26.

Accession Number: 20261021–5215.

Comment Date: 5 p.m. ET 11/12/26.

Docket Numbers: ER22–2357–003.

Applicants: ISO New England Inc., Eversource Energy Service Company (as agent), Cross-Sound Cable Company, LLC, New England Power Pool Participants Committee, The United Illuminating Company.

Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: Compliance Filing; Notice of Effective Date for Order No. 881 to be effective N/A.

Filed Date: 10/23/26.

Accession Number: 20261023–5092.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER25–410–001.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: Compliance filing: ISO New England Inc. submits tariff filing per 35: Compliance Filing; Notice of Effective Date for Order No. 881 to be effective N/A.

Filed Date: 10/23/26.

Accession Number: 20261023–5094.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER26–3028–000.

Applicants: PJM Interconnection, L.L.C., Buckeye Power, Inc.

Description: Refund Report: PJM Interconnection, L.L.C. submits tariff filing per 35.19a(b); Buckeye submits Refund Report in Docket No. ER26–3028 to be effective N/A.

Filed Date: 10/23/26.

Accession Number: 20261023–5119.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER26–3425–001.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing: Notice of Effective Date—Remove MSRs from the Calibration Adjustment Process to be effective 11/1/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5061.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER26–3602–002.

Applicants: Neradean Energy Inc.

Description: Tariff Amendment: Amendment to Deficiency Response—Category 1 Seller Representations to be effective 8/25/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5050.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–251–000.

Applicants: Duke Energy Progress, LLC.

Description: Tariff Amendment: Notice of Cancellation of Contracts in Anticipation of Int Reorg Consummation to be effective 12/31/9998.

Filed Date: 10/22/26.

Accession Number: 20261022–5173.

Comment Date: 5 p.m. ET 11/12/26.

Docket Numbers: ER27–252–000.

Applicants: California Grid Holdings LLC.

Description: 205(d) Rate Filing: Revisions to Appendix I of Transmission Owner Tariff to be effective 1/1/2027.

Filed Date: 10/23/26.

Accession Number: 20261023–5062.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–253–000.

Applicants: Egypt Road Solar, LLC.

Description: 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 10/24/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5068.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–254–000.

Applicants: Morgnac Road Solar, LLC.

Description: 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 10/24/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5070.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–255–000.

Applicants: Spring Grove Solar II, LLC.

Description: 205(d) Rate Filing: Revised Market-Based Rate Tariff to be effective 10/24/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5071.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–256–000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 4195R1 Northern Divide Energy Storage GIA to be effective 12/23/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5079.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–257–000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 4318R1 SPS GIA to be effective 10/1/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5086.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–258–000.

Applicants: Southwest Power Pool, Inc.

Description: 205(d) Rate Filing: 5017 Hickory Creek Project GIA to be effective 9/24/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5093.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–259–000.

Applicants: Midcontinent

Independent System Operator, Inc.,
Hoosier Energy Rural Electric
Cooperative.

Description: 205(d) Rate Filing:

Hoosier Energy Rural Electric
Cooperative submits tariff filing per
35.13(a)(2)(iii): 2026–10–23 Hoosier
Energy Transition to Forward Looking
Attachment O to be effective 1/1/2027.

Filed Date: 10/23/26.

Accession Number: 20261023–5095.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–260–000.

Applicants: Pacific Gas and Electric
Company.

Description: 205(d) Rate Filing: RS
242: Work Performance Agreement for
WAPA Cottonwood to be effective 10/
31/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5101.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–261–000.

Applicants: Midcontinent
Independent System Operator, Inc.

Description: 205(d) Rate Filing: 2026–
10–23 SA 4876 Big Rivers-Nebo Energy
GIA (S1073) to be effective 10/16/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5138.

Comment Date: 5 p.m. ET 11/13/26.

Docket Numbers: ER27–262–000.

Applicants: Anchor Point Central,
LLC.

Description: 205(d) Rate Filing:
Baseline new to be effective 12/23/2026.

Filed Date: 10/23/26.

Accession Number: 20261023–5156.

Comment Date: 5 p.m. ET 11/13/26.

The filings are accessible in the
Commission's eLibrary system ([https://
elibrary.ferc.gov/idmws/search/
fercgensearch.asp](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](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](mailto:OPP@ferc.gov).

Dated: October 23, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–21987 Filed 10–27–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26–549–000]

ETC Tiger Pipeline, LLC; Notice of Schedule for the Preparation of an Environmental Assessment for the Franklin Farms Project

On July 1, 2026, ETC Tiger Pipeline,
LLC (ETC Tiger) filed an application in
Docket No. CP26–61–000 requesting a
Certificate of Public Convenience and
Necessity pursuant to Section 7c of the
Natural Gas Act to construct and operate
certain natural gas facilities. The
proposed project, known as the Franklin
Farms Project (Project), would enable
ETC Tiger to provide Entergy Louisiana,
LLC with 250,000 dekatherms per day of
firm transportation service mainline
capacity and 1,000,000 dekatherms per
day of capacity on a newly constructed
lateral for a new artificial intelligence
data center campus in Richland Parish,
Louisiana.

On July 16, 2026, the Federal Energy
Regulatory Commission (Commission or
FERC) issued its Notice of Application
for the Project. Among other things, that
notice alerted agencies issuing federal
authorizations of the requirement to
complete all necessary reviews and to
reach a final decision on a request for
a federal authorization within 90 days of
the date of issuance of the Commission
staff's environmental document for the
Project.

This notice identifies Commission
staff's intention to prepare an
environmental assessment (EA) for the
Project and the planned schedule for the
completion of the environmental
review.¹ The EA will be issued for a 30-
day comment period.

Schedule for Environmental Review

Issuance of EA January 8, 2027

¹ For tracking purposes under the National
Environmental Policy Act, the unique identification
number for documents relating to this
environmental review is EAXX–019–20–000–
1788263742.

90-day Federal Authorization Decision
Deadline² April 8, 2027

If a schedule change becomes
necessary, additional notice will be
provided so that the relevant agencies
are kept informed of the Project's
progress.

Project Description

ETC Tiger is proposing to construct
and operate the following facilities in
Richland Parish, Louisiana:

- approximately 13.2 miles of new
36-inch-diameter greenfield pipeline
(Franklin Farms Lateral);
 - approximately 1.75 miles of 20-
inch-diameter pipeline lateral (Franklin
Farms Trio Farm Lateral);
 - the Franklin Farms, Bee Bayou, and
Trio Farm Delivery Meter Stations;
 - the Midcontinent Express, Gulf
South, and Gulf Crossing Receipt Meter
Stations and the Gulf Run Bi-directional
Meter Station;
 - the Franklin Farms Interconnect;
- and
- three new mainline valves and
other related appurtenant facilities.

Background

On August 25, 2026, the Commission
issued a *Notice of Scoping Period
Requesting Comments on
Environmental Issues for the Proposed
Franklin Farms Project* (Notice of
Scoping). The Notice of Scoping was
sent to affected landowners; federal,
state, and local government agencies;
elected officials; Native American tribes;
environmental and public interest
groups; other interested parties; local
libraries, and media outlets. To date, the
Commission has received comments
from the Sierra Club, one individual, the
U.S. Environmental Protection Agency,
and Restore Explicit Symmetry To Our
Ravaged Earth (RESTORE). The primary
issues raised by the Sierra Club are
concerns regarding alternatives, adverse
effects on land use, water resources and
water quality, wetlands, wildlife
habitats, migratory birds, endangered
species, soil erosion, air quality, and
noise. The individual filed a comment
opposed to the project and raised
concerns about increased energy costs
consumers. The U.S. Environmental
Protection Agency recommended that
the environmental document address
water quality, groundwater, National

² The Commission's deadline applies to the
decisions of other federal agencies, and state
agencies acting under federally delegated authority,
that are responsible for federal authorizations,
permits, and other approvals necessary for
proposed projects under the Natural Gas Act. Per
18 CFR 157.22(a), the Commission's deadline for
other agency's decisions applies unless a schedule
is otherwise established by federal law.

Pollutant Discharge Elimination System permit coverage, ambient air conditions and air quality effects, and solid and hazardous waste generated. RESTORE filed comments regarding concerns of geological hazards impacting the pipeline and related impacts from the new Data Center in the project area. All substantive comments will be addressed in the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

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.

Additional information about the Project is available from the FERC website (www.ferc.gov). Using the “eLibrary” link, select “General Search” from the eLibrary menu, enter the selected date range and “Docket Number” excluding the last three digits (i.e., CP26-549), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208-3676, TTY (202) 502-8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

(Authority: 18 CFR 2.1.)

Dated: October 23, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-21989 Filed 10-27-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2711-025]

Northern States Power Company; Notice of Intent To Prepare an Environmental Assessment

On November 30, 2023, Northern States Power Company filed a relicense application for the 1.2-megawatt Trego Hydroelectric Project

No. 2711 (project). The project is located on the Namekagon River in Washburn County, Wisconsin.

In accordance with the Commission's regulations, on July 7, 2026, Commission staff issued a notice that the project was ready for environmental analysis (REA notice). Based on the information in the record, including comments filed on the REA Notice, staff does not anticipate that licensing the project would constitute a major federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an environmental assessment (EA) on the application to relicense the project.¹

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

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 application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA ...	July 30, 2027.

Any questions regarding this notice may be directed to Laura Washington Laura.Washington@ferc.gov, or 202-502-6072.

(Authority: 18 CFR 2.1)

Dated: October 23, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-21990 Filed 10-27-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2417-067]

Northern States Power Company; Notice of Intent To Prepare an Environmental Assessment

On November 30, 2023, Northern States Power Company filed a relicense application for the 0.168-megawatt Hayward Hydroelectric

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1789562018.

Project No. 2417 (project). The project is located on the Namekagon River in Sawyer County, Wisconsin.

In accordance with the Commission's regulations, on July 7, 2026, Commission staff issued a notice that the project was ready for environmental analysis (REA notice). Based on the information in the record, including comments filed on the REA Notice, staff does not anticipate that licensing the project would constitute a major federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an environmental assessment (EA) on the application to relicense the project.¹

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

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 application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA.	July 30, 2027.

Any questions regarding this notice may be directed to Laura Washington Laura.Washington@ferc.gov, or 202-502-6072.

(Authority: 18 CFR 2.1.)

Dated: October 23, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-21984 Filed 10-27-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26-550-000]

MountainWest Overthrust Pipeline, LLC; Notice of Schedule for the Preparation of an Environmental Assessment for the Green River West Expansion Project

On July 1, 2026, MountainWest Overthrust Pipeline, LLC (Overthrust)

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX-019-20-000-1789561892.

filed an application in Docket No. CP26–550–000 requesting a Certificate of Public Convenience and Necessity pursuant to Section 7(c) of the Natural Gas Act to construct and operate certain natural gas pipeline facilities. The proposed project is known as the Green River West Expansion Project (Project), and it would allow the delivery of up to 64,000 dekatherms per day of firm natural gas transportation service from receipt points near Opal, Wyoming, to the new WE Soda delivery meter station in Sweetwater County, Wyoming.

On July 15, 2026, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for the Project. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's environmental document for the Project.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the Project and the planned schedule for the completion of the environmental review.¹

Schedule for Environmental Review

Issuance of EA February 5, 2027
90-day Federal Authorization Decision
Deadline² May 6, 2027

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project's progress.

Project Description

Overthrust proposes to construct, own, operate, and maintain the following facilities in Sweetwater County, Wyoming: two new 12-inch-diameter delivery taps on Overthrust's existing ML116 and ML133 mainline pipelines; a 6.78-mile-long, 12-inch-diameter tap line (JTL150), extending north from the new taps to WE Soda's Westvaco Trona Processing Plant; and a new meter and regulator station (JTL150 Meter Station) at the existing Westvaco

Plant site. The Project would also involve construction of new permanent access roads, use of existing access roads, and use of temporary workspaces during construction.

Background

On September 1, 2026, the Commission issued a *Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Green River West Expansion Project* (Notice of Scoping). The Notice of Scoping was sent to federal, state, and local government representatives and agencies; elected officials; Native American Tribes; environmental and public interest groups; other interested parties; and local libraries and media outlets. In response to the Notice of Scoping, the Commission received comments from the Wyoming Department of Environmental Quality, Water Quality Division and the U.S. Bureau of Land Management, Kemmerer Field Office. The primary issues raised to date are the identification of surface waters of the state in proximity to the Project, their designated uses, and compliance with Wyoming water quality permitting requirements; and effects on wildlife and special status species, vegetation and soils, cultural, paleontological, and land resources on BLM-administered public lands. A letter of support for the project was also filed by the Sweetwater County Board of County Commissioners. All substantive comments will be addressed in the EA.

The U.S. Bureau of Land Management, Kemmerer Field Office is a cooperating agency in the preparation of the EA.

Additional Information

In order to receive notification of the issuance of the EA and to keep track of formal issuances and submittals in specific dockets, the Commission offers a free service called eSubscription. This service provides automatic notification of filings made to subscribed dockets, document summaries, and direct links to the documents. Go to <https://www.ferc.gov/ferc-online/overview> to register for eSubscription.

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.

Additional information about the Project is available from the FERC website (www.ferc.gov). Using the “eLibrary” link, select “General Search” from the eLibrary menu, enter the selected date range and “Docket Number” excluding the last three digits

(i.e., CP26–550), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at FERCOnlineSupport@ferc.gov. The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

(Authority: 18 CFR 2.1)

Dated: October 23, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–21986 Filed 10–27–26; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Revision of Information Collection; FDIC How America Banks Survey; Comment Request (3064–0215)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the survey collection instrument for its tenth biennial survey of households, the FDIC How America Banks Survey (Household Survey).¹ This survey is assigned OMB Control No. 3064–0215. The 2027 Household Survey is scheduled to be conducted in partnership with the U.S. Census Bureau as a supplement to its June 2027 Current Population Survey (CPS). The survey collects information on U.S. households' use of bank accounts, prepaid cards, nonbank online payment services and other nonbank financial transaction services, and bank and nonbank credit. The results of these biennial surveys are published by the FDIC, and help inform policymakers, bankers, and researchers about bank account ownership and how households use the banking system and nonbank financial products and services to meet their financial needs.

DATES: Comments must be submitted on or before December 28, 2026.

ADDRESSES: Interested parties are invited to submit written comments to

¹ For tracking purposes under the National Environmental Policy Act, the unique identification number for documents relating to this environmental review is EAXX–019–20–000–1789542496.

² The Commission's deadline applies to the decisions of other federal agencies, and state agencies acting under federally delegated authority, that are responsible for federal authorizations, permits, and other approvals necessary for proposed projects under the Natural Gas Act. Per 18 CFR 157.22(a), the Commission's deadline for other agency's decisions applies unless a schedule is otherwise established by federal law.

¹ The FDIC How America Banks Survey was formerly known as the FDIC National Survey of Unbanked and Underbanked Households.

the FDIC by any of the following methods:

- *Agency Website:* <https://www.fdic.gov/resources/regulations/federal-register-publications/>.
- *Email:* comments@fdic.gov. Include the name and number of the collection in the subject line of the message.
- *Mail:* Robert Meiers, Regulatory Attorney (571 645 3062), MB-3013, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to "Household Survey." A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

Robert Meiers, Regulatory Attorney, (571) 645-3062, romeiers@fdic.gov, MB-3013, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: The FDIC is requesting OMB approval for the following collection of information:

Title: FDIC How America Banks Survey.

OMB Number: 3064-0215.

Frequency of Response: Once.

Affected Public: Individuals residing in U.S. Households.

Estimated Number of Respondents: 40,000.

Average Time per Response: 9 minutes (0.15 hours) per respondent.

Estimated Total Annual Burden: 6,000 hours.

General Description of Collection: The FDIC recognizes that access to a bank account is essential for Americans to participate in many aspects of the economy. As part of its mission of maintaining the stability of and public confidence in the U.S. financial system, the FDIC has a longstanding goal of ensuring Americans can access and benefit from bank accounts. The FDIC How America Banks Survey (Household Survey) is one avenue by which the FDIC responds to a Congressional mandate contained in section 7 of the Federal Deposit Insurance Reform Conforming Amendments Act of 2005 (Reform Act) (Pub. L. 109-173) for the FDIC to conduct ongoing surveys "on efforts by insured depository institutions to bring those individuals and families who have rarely, if ever,

held a checking account, a savings account or other type of transaction or check cashing account at an insured depository institution (hereafter in this section referred to as the "unbanked") into the conventional finance system." Section 7 further instructs the FDIC to consider several factors in its conduct of the surveys, including: (1) "what cultural, language and identification issues as well as transaction costs appear to most prevent 'unbanked' individuals from establishing conventional accounts;" and (2) "what is a fair estimate of the size and worth of the "unbanked" market in the United States."

The Household Survey collects information on bank account ownership which provides a factual basis for measuring the number and percentage of households that are unbanked. It is the only population-representative survey conducted at the national level that provides state-level estimates of the size and characteristics of unbanked households for all 50 States and the District of Columbia. The Household Survey also collects information from unbanked households about the reasons that they do not have a bank account and their interest in having a bank account.

Nonbank financial companies are playing an increasingly important role in the provision of financial products and services in the U.S., and households may use a variety of bank and nonbank financial products and services to meet their needs. Consequently, the Household Survey collects information on whether and how households use a wide range of bank and nonbank financial products and services.

To obtain this information, the FDIC partners with the U.S. Census Bureau, which administers the Household Survey under an FDIC-sponsored supplement to its Current Population Survey (CPS). The Household Survey has been administered every other year since January 2009. The previous survey questionnaires and survey results can be accessed through the following link: <http://fdic.gov/analysis/household-survey>.

Consistent with the statutory mandate to conduct the surveys on an ongoing basis, the FDIC already has in place arrangements for conducting the tenth Household Survey as a supplement to the June 2027 CPS. Prior to finalizing the 2027 survey questionnaire, the FDIC seeks to solicit public comment on whether changes to the existing instrument are desirable and, if so, to what extent. It should be noted that, as a supplement of the CPS survey, the Household Survey needs to adhere to

specific parameters that include limits in the length and sensitivity of the questions that can be asked of CPS respondents. Interested members of the public may obtain a copy of the proposed survey questionnaire on the following web page: <https://www.fdic.gov/resources/regulations/federal-register-publications/2027/2027-household-survey-questionnaire.pdf>.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on October 26, 2026.

Jennifer M. Jones,

Deputy Executive Secretary.

[FR Doc. 2026-21983 Filed 10-27-26; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal

Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than November 27, 2026.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org:

1. *Newington Bancshares, Inc., Newington, Georgia*; to become a bank holding company by acquiring voting shares of Bank of Newington, also of Newington, Georgia.

B. Federal Reserve Bank of Dallas (Lindsey Wieck, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201-2272. Comments can also be sent electronically to Comments.applications@dal.frb.org:

1. *Plains Acquisition Corporation, Humble, Texas*; to acquire Austin Colony, Inc., and thereby indirectly acquire First National Bank of Lake Jackson, both of Lake Jackson, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026-21970 Filed 10-27-26; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Information collection notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the extension without change of the currently approved information collection "Questionnaire and Data Collection Testing, Evaluation, and Research for the Agency for Healthcare Research and Quality" (OMB #0935-0124).

DATES: Comments on this notice must be received by December 28, 2026.

ADDRESSES: Written comments should be submitted to: Margie Shofer, Reports Clearance Officer, AHRQ, by email at REPORTSCLEARANCEOFFICER@ahrq.hhs.gov. Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Margie Shofer, AHRQ Reports Clearance Officer, (301) 427-1696, or by email at REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve the extension without change of "Generic Clearance for Questionnaire and Data Collection Testing, Evaluation, and Research" (0935-0124) for three years to facilitate AHRQ's efforts to (1) employ evaluation-type methods and techniques to improve AHRQ's current data collection and estimation procedures, (2) develop new collections and procedures, including toolkits, and (3) revise existing collections and procedures. The current clearance expires on 3/31/2027.

AHRQ uses techniques to simplify data collection and estimation procedures, reduce respondent burden, and improve efficiencies to meet the needs of individuals and small business respondents who may have reduced budgets and staff. AHRQ believes that developing, testing, and evaluating data collection and estimation procedures using survey methods and other techniques in anticipation of agency-sponsored studies can improve its information collection efforts and the products it develops and allow AHRQ to be more responsive to fast-changing developments in the healthcare research field.

This clearance request is limited to research on data collections, toolkit

development, and estimation procedures and reports and does not extend to the collection of data for public release or policy formation.

This generic clearance will allow AHRQ to draft and test toolkits, survey instruments and other data collection and estimation procedures more quickly and with greater lead time, thereby managing project time more efficiently and improving the quality of the data AHRQ collects. In some instances, the ability to test and evaluate toolkits, data collection and estimation procedures in anticipation of work or early in a project may result in the decision not to proceed with additional activities, thereby saving both public and private resources and effectively eliminating respondent burden.

Many of the tools AHRQ develops are made available to the private sector to assist in improving health care quality. The health and health care environment changes rapidly and requires a quick response from AHRQ to provide refined tools. This generic clearance will facilitate AHRQ's response to this changing environment.

These preliminary research activities will not be used by AHRQ to regulate or sanction its customers. They will be entirely voluntary, and the confidentiality of respondents and their responses will be preserved.

Proposed Revisions

No revisions to the currently approved package are being proposed.

Method of Collection

The information collected through preliminary research activities will be used by AHRQ to employ techniques to (1) improve AHRQ's current data collection and estimation procedures, (2) develop new collections and procedures, including toolkits, and/or (3) revise existing collections and procedures in anticipation or in response to changes in the health or health care field. The end result will be improvement in AHRQ's data collections and procedures, and the quality of data collected, a reduction or minimization of respondent burden, increased agency efficiency, and improved responsiveness to the public.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annual burden hours for the respondents' time to participate in the research activities that may be conducted under this generic clearance. Mail surveys will be conducted with about 2,000 respondents per year and are estimated to average 20 minutes. Mail surveys may also be sent to respondents via email

and may include a telephone non-response follow-up. Telephone non-response follow-up for mailed surveys is not counted as a telephone survey in Exhibit 1. About 200 people will participate in telephone surveys that will take about 40 minutes. Web-based surveys will be conducted with about 1,000 people and will require about 10 minutes to complete. About 500 people

will participate in focus groups which may last about two hours, while in-person interviews will be conducted with about 200 people and will take about 1 hour to complete. Automated data collection will be conducted for about 500 people and could take about 1 hour. Cognitive testing will be conducted with about 200 persons and is estimated to take 1½ hours to

complete. The total annual burden hours is 2,967.

Exhibit 2 shows the estimated annual cost burden associated with respondent's time to participate in these research activities. The adjusted annual cost burden is estimated to be \$310,111.

Exhibit 1—Estimated Annualized Burden Hours

Type of information collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Mail/email *	2,000	1	20/60	667
Telephone	200	1	40/60	133
Web-based	1,000	1	10/60	167
Focus Groups	500	1	2.0	1000
In-person	200	1	1.0	200
Automated **	500	1	1.0	500
Cognitive Testing ***	200	1	1.5	300
Totals	4,600	N/A	N/A	2,967

* May include telephone non-response follow-up in which case the burden will not change.

** May include testing of database software, CAPI software or other automated technologies.

*** May include cognitive interviews for questionnaire or toolkit development, or "think aloud" testing of prototype websites.

Exhibit 2—Estimated Annualized Burden Costs

Type of information collection	Total burden hours	Average hourly wage rate *	Adjusted hourly wage rate **	Total adjusted cost burden
Mail/email	667	\$52.26	\$104.52	\$69,715
Telephone	133	52.26	104.52	13,901
Web-based	167	52.26	104.52	17,455
Focus Groups	1000	52.26	104.52	104,520
In-person	200	52.26	104.52	20,904
Automated	500	52.26	104.52	52,260
Cognitive Testing	300	52.26	104.52	31,356
Total	2,967	N/A	N/A	310,111

* U.S. Bureau of Labor & Statistics "Occupational Employment and Wages, May 2025" found at the following URL—<https://data.bls.gov/oes/#/area/0000000/2025>. Occupation series "Healthcare practitioners and technical occupations" (29-0000) was used for estimated average hourly wages in these calculations.

** Adjusted Average Hourly Rate is 200% of the average hourly rate. It is a fully loaded rate that includes the benefit costs of respondents.

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the

respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 23, 2026.

Jeffrey Toven,
Executive Officer.

[FR Doc. 2026–21985 Filed 10–27–26; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–12178]

Notice of Approval of Product Under Voucher: Material Threat Medical Countermeasure (MCM) Priority Review Voucher; Bixlenvo (Bictegravir and Lenacapavir)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a material threat MCM priority review voucher. The Federal Food, Drug, and

Cosmetic Act (the FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the issuance of material threat MCM priority review vouchers as well as the approval of products redeeming a voucher. FDA has determined that Bixlenvo (bictegravir and lenacapavir), tablets, approved August 27, 2026, meet the redemption criteria.

FOR FURTHER INFORMATION CONTACT:

Andrea Gormley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3751, email: Andrea.Vincent@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), which was added by section 3086 of the Cures Act (Pub. L. 114-255), FDA will report the issuance of material threat MCM priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the application for, Bixlenvo (bictegravir and lenacapavir), tablets approved August 27, 2026, meets the redemption criteria.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv>. For further information about Bixlenvo (bictegravir and lenacapavir), tablets go to the “Drugs@FDA” website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-21909 Filed 10-27-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3743]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection applicable to the electronic record signature provisions found in Agency regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by December 28, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2023-N-3743 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Requirements for Nonclinical Laboratory Studies.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s

estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Electronic Records; Electronic Signatures—21 CFR Part 11

OMB Control Number 0910-0303—Extension

This information collection supports implementation of statutory and regulatory authorities that govern criteria for the acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Agency regulations in part 11 (21 CFR part 11), provide for the submission of records and reports and establish that information may be submitted to FDA electronically provided that we have stated our ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met. The regulations apply to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in Agency regulations and to electronic records submitted under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations.

Before using an electronic signature in an electronic record required by FDA, a person must submit a letter of nonrepudiation to FDA (§ 11.100(c)). Letters of nonrepudiation are required under § 11.100(c)(1) to certify that a

person’s electronic signatures are intended to be the legally binding equivalent of traditional handwritten signatures. We provide information on our website at <https://www.fda.gov/industry/electronic-submissions-gateway-next-generation-esg-nextgen> regarding the utilization of electronic submissions, including user guides and training videos. We have also developed the guidance document, “Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (Revision 7),” (September 2024), available for download at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>, to provide instructional assistance pertaining to submitting information to FDA in an electronic format.

Regulations in part 11, subpart B (§§ 11.10 through 11.70) require the establishment of standard operating procedures to ensure appropriate use of and precautions for systems using electronic records and signatures, including the following: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; and (3) § 11.50 specifies procedures and controls for persons who use electronic signatures.

Regulations in subpart C (§§ 11.100 through 11.300) require specific controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 11.100; submission of nonrepudiation letters	5,000	1	5,000	1	5,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR section	Number of recordkeepers	Number of record per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
§ 11.10; controls for closed systems	2,500	1	2,500	20	50,000
§ 11.30; controls for open systems	2,500	1	2,500	20	50,000
§ 11.50; signature manifestations	5,000	1	5,000	20	100,000

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹—Continued

21 CFR section	Number of recordkeepers	Number of record per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
§ 11.300; controls for identifications and passwords	5,000	1	5,000	20	100,000
Total					300,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We continue to assume 5,000 nonrepudiation letters will be submitted annually. We arrived at this figure by looking at the average number of nonrepudiation letters received over the past 3 years. We also assume that half of the estimated respondents will establish controls for open systems and half will establish controls for closed systems. Finally, we assume all respondents will establish controls for the remaining technical specifications required by the regulations.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2026–21908 Filed 10–27–26; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–11783]

Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document titled “Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management.” The draft guidance document provides recommendations for how an individualized human genome editing (GE) product that includes multiple product variants can be submitted in a single Biologics License Application (BLA). When finalized, this guidance will describe the FDA’s current thinking on individualized GE products with respect to how to specify the extent of GE component variation in a BLA, how to add new product variants to the BLA after licensure, and related topics.

DATES: Submit either electronic or written comments on the draft guidance by November 27, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–

2026–D–11783 for “Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Janet Goldberg, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document titled “Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management.” The draft guidance document, intended for sponsors and applicants developing individualized GE products, provides recommendations for how an individualized GE product that includes multiple product variants can be submitted in a single BLA under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)). When finalized, this guidance will describe FDA’s current thinking regarding how to specify the extent of GE component variation in a BLA and how to add new product variants to the BLA after licensure. This guidance also addresses related topics, including potency and safety evaluation of product variants, manufacturing process validation, labeling and indication statements, and drug naming and identification. This guidance is intended to complement existing FDA guidances on GE products addressing investigational new drug (IND)-stage chemistry, manufacturing, and controls (CMC); nonclinical and clinical trial design; evidentiary standards for approval of individualized therapies; and leveraging of CMC, nonclinical, and clinical knowledge across GE programs^{1 2 3} with additional

advice and considerations on how to prepare and submit BLAs and BLA supplements for individualized GE products.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR parts 210 and 211 pertaining to manufacturing, processing, packing, and holding of finished pharmaceuticals and biological products for human use (CGMP regulations) have been approved under OMB control number 0910-0139. The collections of information in 21 CFR 312.23(a)(7)(i) pertaining to submission of proper identification, quality, purity, and strength of an investigational drug in an IND application have been approved under OMB control number 0910-0014. The collections of information in 21 CFR 600.14(b) pertaining to biological product deviation reporting is included in OMB control number 0910-0458. The collections of information in 21 CFR part 601 pertaining to biological license applications have been approved under OMB control number 0910-0338.

to Develop Individualized Therapies that Target Specific Genetic Conditions with Known Biological Cause,” February 2026, <https://www.fda.gov/media/191247/download>. When finalized, this guidance will represent FDA’s current thinking on this topic.

³ See Draft Guidance for Industry “Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing,” June 2026, <https://www.fda.gov/media/192810/download>. When finalized, this guidance will represent FDA’s current thinking on this topic.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-21954 Filed 10-27-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-11980]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; ATEBRIQ (Zilurgisertib)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ATEBRIQ (zilurgisertib), approved September 25, 2026, manufactured by Incyte Corporation meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Scott Winiecki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-771-1519, Scott.Winiecki@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined ATEBRIQ (zilurgisertib), manufactured by Incyte Corporation meets the criteria for a priority review voucher.

¹ See Guidance for Industry “Human Gene Therapy Products Incorporating Human Genome Editing,” January 2024, <https://www.fda.gov/media/156894/download>.

² See Draft Guidance for Industry “Considerations for the Use of the Plausible Mechanism Framework

ATEBRIOZ (zilurgisertib) tablets for oral use is indicated to reduce the volume of total new heterotopic ossification (HO) in adults and pediatric patients aged 12 years and older with fibrodysplasia ossificans progressiva (FOP).

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseaseConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ATEBRIOZ (zilurgisertib), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21910 Filed 10–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–12279]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; EMCITATE (Tiratricol)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that EMCITATE (tiratricol), approved September 28, 2026, manufactured by Rare Thyroid Therapeutics International AB meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Scott Winiecki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Silver Spring, MD 20993–0002, 301–771–1519 Scott.Winiecki@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product

application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined EMCITATE (tiratricol), manufactured by Rare Thyroid Therapeutics International AB meets the criteria for a priority review voucher. EMCITATE (tiratricol) tablet is indicated for the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency (Allan-Herndon-Dudley syndrome).

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about EMCITATE (tiratricol) go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21911 Filed 10–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–11188]

Electronic Submission Template for Investigational Device Exemption (IDE) Applications; Draft Guidance for Sponsors and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance titled “Electronic Submission Template for Investigational Device Exemption (IDE) Applications.” FDA is issuing this draft guidance for sponsors submitting IDE applications to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). It introduces those sponsors to the current publicly available resources and associated content developed to support IDE electronic submissions to FDA. This draft guidance, when finalized, is intended to represent one of several

steps in meeting FDA’s commitment to the development of electronic submission templates to serve as guided submission preparation tools for sponsors to improve submission consistency and enhance efficiency in the review process. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 28, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2026–D–11188 for “Electronic

Submission Template for Investigational Device Exemption (IDE) Applications.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document titled “Electronic Submission Template for Investigational Device

Exemption (IDE) Applications” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–6353; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance document to introduce sponsors submitting IDE applications to CDRH and CBER to the current resources and associated content developed and made publicly available to support the electronic submissions of Original IDE applications, IDE supplemental applications, and amendments to Original IDE and IDE supplemental applications, and related IDE submissions to FDA. This draft guidance is intended to represent one of several steps in meeting FDA’s commitment to the development of electronic submission templates to serve as guided submission preparation tools for sponsors to improve submission consistency and enhance efficiency in the review process. When finalized, this guidance will also facilitate the implementation of the FDA’s mandate under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52), to provide further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

FDA’s final guidance document published on July 15, 2020 (85 FR 42864): “Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act” (hereafter referred to as the “745A(b) device parent guidance”) provides a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in electronic format. As described in the 745A(b) device parent guidance, FDA plans to implement the requirements of section 745A(b)(3) of the FD&C Act with

individual guidances specifying the formats for specific submissions and corresponding timetables for implementation. When finalized, this guidance will provide such information for IDE electronic submissions solely in electronic format.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this draft guidance provides such requirements under section 745A(b)(3) of the FD&C Act (*i.e.*, standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as *must* or *required*, this document is not subject to the usual restrictions in FDA’s good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see § 10.115(d)). To the extent that this draft guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3) of the FD&C Act, it is being issued consistent with FDA’s good guidance practices regulation (§ 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on Electronic Submission Template for IDE Applications. With the exception of the guidance’s provision of requirements for “standards,” “timetable,” or “criteria for waivers” and “exemptions” pursuant to section 745A(b) of the Federal Food, Drug, and Cosmetic Act, it does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>.

www.fda.gov/regulatory-information/search-fda-guidance-documents, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Electronic Submission Template for Investigational Device Exemption (IDE) Applications” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00007080 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part	Topic	OMB control No.
812 ...	Investigational Device Exemption.	0910–0078
820 ...	Current Good Manufacturing Practice (CGMP); Quality Management System Regulation (QMSR).	0910–0073

Grace R. Graham,
Deputy Commissioner for Policy, Legislation,
and International Affairs.
[FR Doc. 2026–21953 Filed 10–27–26; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–2742]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Color Additive Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 27, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0216. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Color Additive Certification

OMB Control Number 0910–0216—Extension

This information collection supports FDA regulations governing certification for color additives used in foods, drugs, cosmetics, and medical devices. All color additives must have FDA-approval for their intended use and be listed in the color additive regulations before they are permitted for use in food, drugs, cosmetics, and many medical devices. Some color additives have an additional requirement: they are permitted only if they are from batches that FDA has certified under section 721(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(a)). This means that FDA chemists have analyzed a sample from the batch and have found that it meets the requirements for composition and purity stated in the regulation, called a “listing regulation,” for that color additive. We list color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). We require batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are established in 21 CFR part 80. Procedures for color additive certification are set forth in part 80, subpart B (§§ 80.21 through 80.39) and communicate required data elements for requests for certification, limitations of certificates, exemptions from certification for color additive mixtures, treatment of batches pending and after certification, and recordkeeping requirements for respondents to whom a certificate is issued. During the batch certification procedure, a manufacturer of color additives must submit a “request for certification” that provides information about the batch, accompanied by a representative sample of a new batch of color additive, to FDA’s Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certificate that contains a certification lot number for the batch. The batch can then be used in FDA-regulated products marketed in the United States, in compliance with the uses and restrictions in that color additive’s listing regulation. If the sample does not meet the requirements, the batch will be rejected. We require manufacturers to keep complete records showing disposal of all of the color additive covered by the certification.

FDA’s web-based color certification information system is available for respondents to request color certification online, track their submissions, and obtain account status information. Prior to submitting a request for certification, the manufacturer must open a color certification account by sending a letter, as an email attachment, signed by responsible company representative, to FDA’s Office of Cosmetics and Colors at color.cert@fda.hhs.gov. System certification results are returned electronically, allowing submitters to sell their certified color before receiving hard copy certificates.

We charge a fee for certification based on the batch weight and require manufacturers to keep records of the batch pending and after certification. The user fees support FDA’s color certification program. Additional information about color additive certification is available at: <https://www.fda.gov/industry/color-additives/color-certification>.

The purpose for collecting this information is to help the Agency assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States.

Description of Respondents: The respondents include businesses engaged in the manufacture of color additives used in FDA-regulated foods, drugs, cosmetics, and medical devices.

Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of March 10, 2026 (91 FR 18464), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
80.21 and 80.22; Request for certification accompanied by sample.	67	112	7,504	0.22 (13 minutes)	1,651

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
80.39; Record of distribution	67	112	7,504	0.25 (15 minutes)	1,876

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate on our review of the certification requests received over the past 3 years. Using information from industry personnel, we estimate that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21913 Filed 10–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–11623]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of

1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of rapid response surveys to obtain data on safety information that supports quick turnaround decision making about potential safety problems or risk management solutions.

DATES: Either electronic or written comments on the collection of information must be submitted by December 28, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2026–N–11623 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Rapid Response Surveys.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket

and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management

Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.
FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Food and Drug Administration Rapid Response Surveys

OMB Control Number 0910–0500—Extension

This generic information collection supports research conducted by FDA, as authorized under section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

FDA is requesting extension of OMB approval to conduct rapid response surveys (RRS). Through these surveys, FDA seeks to determine whether a problem impacts public health and to quickly obtain vital information about risks and interventions. FDA will use the information gathered from these surveys to make timely decisions about safety problems or risk management solutions so the Agency may take appropriate public health action including dissemination of information as necessary. Participation in these surveys is voluntary.

Respondents may include manufacturers and distributors of biologics, drugs, food, animal food and drugs, dietary supplements, food additives, cosmetics, medical devices, and tobacco products; sponsors and importers; consumers; healthcare professionals; hospitals; specialized medical facilities (e.g., cardiac surgery, obstetrics/gynecology services, and pediatric services) and other user facilities including nursing homes, ambulatory surgical and outpatient diagnostic and treatment facilities when FDA must quickly determine whether or not a problem impacts the public health. Once FDA determines that additional surveillance data are needed to address a potential public health hazard, the appropriate respondents will be identified for each individual RRS.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA Rapid Response Surveys	10,000	1	10,000	0.5 (30 minutes)	5,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21912 Filed 10–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–11301]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs.”

DATES: Either electronic or written comments on the collection of information must be submitted by December 28, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 28, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the

instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2026–N–11301 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS

CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5661, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs
OMB Control Number 0910–0780—Extension
This information collection supports FDA programs. The FDA has established fellowship and traineeship programs to train scientists in intramural research and/or review. Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code, provides authorization for federal agencies to collect applications for Federal positions. These voluntary online applications for FDA traineeship and fellowship programs will allow FDA to easily and efficiently solicit and review information from students and

health care professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA. Section 746(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b)) authorizes FDA to provide non-employees with intramural research training and support all aspects of the program to include collection of application materials.
FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Medical Device Fellowship Program	250	1	250	1	250
FDA Traineeship Program	1,000	1	1,000	1	1,000
Total					1,250

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.
Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2026–21914 Filed 10–27–26; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.
The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; International Research Collaborations Projects.
Date: November 16, 2026.
Time: 9:00 a.m. to 11:00 a.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: Carlos J. Perez-Torres, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–0451, carlos.perez-torres@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 26, 2026.
Sterlyn H. Gibson,
Program Specialist, Office of Federal Advisory Committee Policy.
[FR Doc. 2026–21973 Filed 10–27–26; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Biomedical Imaging and Bioengineering; 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 Advisory Council for Biomedical Imaging and Bioengineering.
The meeting will be open to the public by videocast. The videocast link is <https://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 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 Advisory Council for Biomedical Imaging and Bioengineering.
Date: January 21, 2027.

Open: January 21, 2027, 12:00 p.m. to 4:00 p.m.

Agenda: Report from the Institute Director, Council Members, and other Institute staff.

Address: National Institutes of Health, Building 31, 9000 Rockville Pike, Room 1C14, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Closed: January 21, 2027, 4:10 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Address: National Institutes of Health, Building 31, 9000 Rockville Pike, Room 1C14, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: David Rampulla, Ph.D., Deputy Director, National Institute of Biomedical Imaging and Bioengineering, 9000 Rockville Pike, Bldg. 31, Room 1C14, Bethesda, MD 20892-5477, 301.451.4774, david.rampulla@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 Institute's/Center's home page: <https://www.nibib.nih.gov/about-nibib/advisory-council>, where an agenda and any additional information for the meeting will be posted when available.

Dated: October 23, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-21974 Filed 10-27-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Vaccine Research Center Board of Scientific Counselors, National Institute of Allergy and Infectious Diseases.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute Of Allergy And Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would

constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Vaccine Research Center Board of Scientific Counselors.

Date: December 17-18, 2026.

Time: 8:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Address: Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 40 Convent Drive, Room 1100, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sarah J. Austin, Acting Deputy Associate Director for Management and Operations, Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 40 Convent Drive, Room 1100, Bethesda, MD 20892, (301) 761-7187, austinsj@niaid.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.

Dated: October 23, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-21975 Filed 10-27-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Advisory Council on Aging.

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 Advisory Council on Aging.

Date: January 26-27, 2027.

Closed: January 26, 2027, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute on Aging 5601 Fishers Lane, Room 8C11 Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Open: January 27, 2027, 10:00 a.m. to 2:00 p.m.

Agenda: Call to order and report from the Director; Working Group on Program; Program Highlights; Council Speaker; Intramural Program Report.

Address: National Institute on Aging 5601 Fishers Lane, Room 8C11 Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Closed: January 27, 2027, 2:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate the Intramural Research Program.

Address: National Institute on Aging 5601 Fishers Lane, Room 8C11 Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Kenneth Santora, Ph.D., Director, Office of Extramural Activities, National Institute on Aging, National Institutes of Health, 5601 Fishers Lane, Room 8C11, Rockville, MD 20852 (301) 496-9322, ksantora@nih.gov.

In the interest of security, NIH has procedures at <https://security.nih.gov/visitors/Pages/visitor-campus-access.aspx> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: www.nia.nih.gov/about/naca, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 23, 2026.

Margaret N. Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-21976 Filed 10-27-26; 8:45 am]

BILLING CODE 4167-05-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2026–0070]

Recertification of Prince William Sound Regional Citizens' Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: The Coast Guard announces the recertification of the Prince William Sound Regional Citizen's Advisory Council (PWSRCAC) as an alternative voluntary advisory group for Prince William Sound, Alaska for a period of March 1, 2026 through February 28, 2027. Under the Oil Pollution Act of 1990 (OPA 90), the Coast Guard may recertify the PWSRCAC on an annual basis. This certification allows PWSRCAC to monitor the activities of terminal facilities and crude oil tankers under an alternative composition as established by OPA 90 statute.

DATES: This recertification is effective for the period from March 1, 2026 through February 28, 2027.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email LT Case Kuikhoven, United States Coast Guard Arctic District; telephone 907–463–2809, email case.a.kuikhoven@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

On December 31, 1992, the Coast Guard published Guidelines for Recertification of Alternative Voluntary Groups In Lieu of a Council (57 FR 62600) to assist groups seeking recertification under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (33 U.S.C. 2732) (the OPA 90 Act). On July 7, 1993, the Coast Guard published a notice (58 FR 36504) identifying the factors that the Coast Guard would consider in making its determination as to whether advisory groups should be certified in accordance with the OPA 90 Act, and the procedures which the Coast Guard would follow in meeting its recertification responsibilities under the OPA 90 Act. On September 16, 2002, the Coast Guard published revised recertification procedure for alternative voluntary advisory groups established in lieu of councils (67 FR 58440). According to the revised procedures, an applicant alternative group requesting recertification is required to provide the Coast Guard with a comprehensive application once every 3 years (triennially). For each of the two years

between the triennial application procedures, the applicant utilizes a streamlined process and submits a recertification application describing any substantive changes to the information provided at the previous triennial recertification. Public comment is only solicited during the triennial comprehensive review. 2026 is the year in this triennial cycle that PWSRCAC must provide comprehensive information.

II. Discussion of Comments

On February 2, 2026, the Coast Guard published a Notice; Request for comments titled “Application for Recertification of Prince William Sound Regional Citizens' Advisory Council” in the **Federal Register** (91 FR 4575). The Coast Guard received 70 comments from Alaska residents, former members of the Prince William Sound Regional Citizen's Advisory Council (PWSRCAC), educational institutions, government agencies, local business owners, Alaska State Legislators and Senators, and a former Governor of Alaska. All comments supported the recertification of the PWSRCAC. Commenters expressed strong support for the Council's work and highlighted its ongoing efforts and contributions. No comments proposed changes to the recertification.

Recertification

By letter dated May 28, 2026, the Commander, Coast Guard Arctic District, certified that the PWSRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on February 28, 2027.

R.R. Little,

Rear Admiral, U.S. Coast Guard, Commander, United States Coast Guard Arctic District.

[FR Doc. 2026–21951 Filed 10–27–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2026–0232; OMB No. 1660–0004]

Agency Information Collection Activities: Submission for OMB Review, Comment Request; Application for Participation in the National Flood Insurance Program

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

ACTION: 30-Day notice of extension and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. FEMA invites the general public to take this opportunity to comment on an extension of a currently approved information collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, this notice seeks comments concerning the collection of information under which communities submit information to FEMA for application and continued participation in the National Flood Insurance Program (NFIP).

DATES: Comments must be submitted on or before November 27, 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:

Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address FEMA-Information-Collections-Management@fema.dhs.gov or Charles Baker, Program Analyst, Floodplain Management Division at charles.baker@fema.dhs.gov or (202) 600–1885.

SUPPLEMENTARY INFORMATION: The NFIP, codified at 42 U.S.C. 4001 *et seq.*, requires all flood-prone communities throughout the country to apply for participation in the NFIP one year after their flood-prone status is identified or submit to the prohibition of certain types of federal and federally related financial assistance for use in their floodplains. 44 CFR 59.2 authorizes previously unavailable flood insurance protection to property owners in flood-prone areas and identifies the information that communities are required to submit to FEMA for application into the NFIP. 44 CFR 59.22 and 59.24 identify the information a community is required to submit to FEMA for continued participation in the program. This collection also accounts for the burden hours associated with the applicant's time to collect information

as part of the community development permit process. To qualify for the NFIP, a participating community must adopt certain minimum standards in accordance with FEMA's regulations at 44 CFR 60.3, 60.4, and 60.5. To verify whether communities maintain such standards, the NFIP requires participating communities to retain documentation on development taking place in the flood hazard areas within the community. See 44 CFR 59.22. Such information will be made available to FEMA upon request. This information assists FEMA in evaluating the effectiveness of a community's floodplain management program and participating property owners' eligibility for flood insurance. The "Application for Participation in the NFIP" and the "NFIP and the Community Development Permit Process" are separate actions documented under the same collection.

This proposed information collection previously published in the **Federal Register** on July 30, 2026, at 91 FR 48400 with a 60-day public comment period. Two public comments were received. One public comment suggested a ceiling on the value of properties eligible for flood insurance, and the other was supportive of this information collection. One comment is not relevant to this information collection, and the other is supportive of its renewal. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Application for Participation in the National Flood Insurance Program.

Type of Information Collection: Extension, without change, of a currently approved information collection.

OMB Number: 1660-0004.

FEMA Forms: FEMA Form FF-206-FY-22-160 (formerly 086-0-30), Application for Participation in the National Flood Insurance Program.

Abstract: The NFIP provides flood insurance to communities that apply for participation and make a commitment to protect against future flood damages. The application form and supporting documentation will enable FEMA to continue to rapidly process new community applications and to thereby more quickly provide flood insurance protection to the residents in communities.

Affected Public: State, Local and Tribal Governments.

Estimated Number of Respondents: 22,792.

Estimated Number of Responses: 91,033.

Estimated Total Annual Burden Hours: 273,144.

Estimated Total Annual Respondent Cost: \$28,704,703.

Estimated Respondents' Operation and Maintenance Costs: \$0.

Estimated Respondents' Capital and Start-Up Costs: \$0.

Estimated Total Annual Cost to the Federal Government: \$120,081.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (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.

Nigel S. Allicock,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.
[FR Doc. 2026-21941 Filed 10-27-26; 8:45 am]

BILLING CODE 9111-47-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-HQ-MB-2026-4291; FXMB1231099BPP0-278-FF09M32000; OMB Control Number 1018-0171]

Agency Information Collection Activities; Establishment of Annual Migratory Bird Hunting Seasons

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an

existing information collection without change.

DATES: Comments will be accepted on or before December 28, 2026. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. To ensure your comment is received and considered, you must submit it using one of the methods identified in the **ADDRESSES** section of this document. Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered.

ADDRESSES:

Comment submission: All submissions must include the docket number [FWS-HQ-MB-2026-4291] for this document. You must submit comments using one of the following methods:

- **Electronic submission:** Federal eRulemaking Portal at: <https://www.regulations.gov>. In the Search box, enter FWS-HQ-MB-2026-4291, which is the docket number for this action. Then click the Search button. On the resulting page, you may submit a comment by clicking on "Comment." Please ensure that you have found the correct document before submitting your comments.

- **U.S. mail:** Service Information Collection Clearance Officer, Attn: Docket No. FWS-HQ-MB-2026-4291, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041-3803.

Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered. We will not accept comments via email, fax, or hand delivery. We are not required to consider comments that are submitted after the comment period ends or that are submitted via a method outside of these instructions. Comments containing profanity, vulgarity, threats, or other inappropriate content will not be considered. We will post all comments at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Madonna Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358-2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1-800-877-8339 for TTY assistance. You may also view the information collection request (ICR) at <http://www.reginfo.gov/public/do/PRAMain>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

As part of our continuing effort to reduce paperwork and respondent burdens, we are soliciting comments from the public and other Federal agencies on the proposed ICR described below. We are especially interested in public comments addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment—including your personally identifiable information—may be publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Abstract: Migratory game birds are those bird species so designated in conventions between the United States and several foreign nations for the protection and management of these birds. Under the Migratory Bird Treaty Act (16 U.S.C. 703–712), the Secretary of the Interior is authorized to determine when “hunting, taking, capture, killing, possession, sale, purchase, shipment, transportation, carriage, or export of any such bird, or

any part, nest, or egg” of migratory game birds can take place, and to adopt regulations for this purpose. These regulations are written after giving due regard to “the zones of temperature and to the distribution, abundance, economic value, breeding habits, and times and lines of migratory flight of such birds” (16 U.S.C. 704(a)). This responsibility has been delegated to the Service as the lead Federal agency for managing and conserving migratory birds in the United States. However, migratory bird management is a cooperative effort of State, Tribal, and Federal governments. Migratory game bird hunting seasons provide opportunities for recreation and sustenance; aid Federal, State, and Tribal governments in the management of migratory game birds; and permit harvests at levels compatible with migratory game bird population status and habitat conditions.

The Service adopted general regulations for migratory game bird hunting, which are set forth in title 50 of the Code of Federal Regulations (CFR) at 50 CFR part 20. These regulations provide that the Service will establish the conditions (limits) from which States and Tribes may establish their seasonal migratory game bird hunting regulations. The limits include season dates, season lengths, shooting hours, bag and possession limits, areas where migratory game bird hunting may occur, and other restrictions, and are communicated via the Migratory Game Bird Hunting (MGBH) Memorandum and notice of availability in the **Federal Register**. These limits are necessary to allow harvest at levels compatible with migratory game bird population status and habitat conditions. After the limits are established, States and Tribes may establish their migratory game bird hunting regulations within the limits and in accordance with our general regulations at 50 CFR part 20. We provided a detailed overview of the process for establishing the Federal limits for seasonal migratory game bird hunting in the August 31, 2026, **Federal Register** (91 FR 55794).

Migratory game birds use four primary migratory routes in North America. Because of the unique biological characteristics and the relative number of hunters in these routes, the Service adopted the flyway structure for administering migratory bird resources within the United States, referred to as the flyways (Atlantic, Mississippi, Central, and Pacific). Each administrative flyway has a Flyway Council established through the Association of Fish and Wildlife Agencies and is composed of one

member from each State and province in that flyway. The Flyway Councils assist in researching and providing migratory game bird management information for Federal, State, Tribal, and provincial governments.

- **State and Territories Seasons**—After the Federal limits are established, States, including the U.S. Territories of Puerto Rico and the Virgin Islands, may establish their migratory game bird hunting regulations within the Federal limits and regulations at 50 CFR part 20.

- **Tribal Seasons**—The Tribal process is very similar to the State process and largely uses the resulting Federal limits developed in the process described above.

Based on the demonstrated successful implementation of our Tribal guidelines since 1985 (50 FR 23467, June 4, 1985), and the historical and future expected minimal impacts to migratory game bird resources, we simplified the process for establishing special Tribal migratory game bird hunting regulations beginning with the (2023–2024) season (88 FR 60375, September 1, 2023). We removed the requirement that Tribes annually submit their proposed migratory game bird hunting regulations (and associated monitoring, anticipated harvest, and capabilities for regulation development and enforcement) for our review and approval. We also no longer publish special Tribal migratory game bird hunting regulations in the **Federal Register** (*i.e.*, a proposed and final rule). The regulations set forth in the 2023 rule adopt elements of our guidelines for establishing special migratory game bird hunting regulations on Federal Indian reservations (including off-reservation trust lands) and ceded lands. Tribes that comply with these regulations are authorized to independently establish special Tribal migratory bird hunting regulations.

By allowing Tribes to independently establish special migratory bird hunting regulations, the Service recognizes Tribal sovereignty to exercise reserved hunting rights and, for some Tribes, recognition of their authority to regulate hunting by both Tribal and nontribal members on their reservation. As an alternative to promulgating special Tribal migratory game bird hunting regulations, Tribes may choose to observe the hunting regulations established by the State or States in which the reservation is located.

For the regulatory cycle, Service biologists gather, analyze, and interpret biological survey data and provide this information to all those involved in the process through a series of published status reports and presentations to the Flyway Councils and other interested

parties. Because the Service is required to take abundance of migratory game birds and other factors into consideration, the Service undertakes a number of surveys throughout the year in conjunction with Service Regional Offices, the Canadian Wildlife Service, and State and provincial wildlife-management agencies. To determine the appropriate limits for each species, we consider factors such as population size and trend, geographical distribution, annual breeding effort, condition of breeding and wintering habitat, number of hunters, and anticipated harvest.

Federal regulations at 50 CFR 20.110 (Regulations for certain Federal Indian reservations and ceded lands) include requirements for Tribes to follow if they establish special Tribal migratory game bird hunting regulations, which are based on elements from the 1985 guidelines. The regulations provide that all Federal hunting regulations in 50 CFR part 20 apply to hunting by Tribal and nontribal members. These regulations provide for the continuation of Tribal members' harvest of migratory game birds on reservations where such harvest is a customary practice. We are supportive of this harvest provided it does not take place during the closed season (March 11 to August 31) mandated by the 1916 Convention Between the United States and Great Britain (for Canada) for the Protection of Migratory Birds and it is not so large as to adversely affect the status of the migratory game bird resource. Since the inception of the 1985 guidelines, we have reached annual agreement with Tribes for migratory game bird hunting by Tribal members on their lands or on lands where they have reserved hunting rights.

We note that migratory game birds are defined in 50 CFR 20.11(a) as those birds included in the terms of conventions between the United States and any foreign country for the protection of migratory birds, belonging to certain families (Anatidae, Columbidae, Gruidae, Rallidae, and Scolopacidae), and for which open seasons are prescribed in this part. Open seasons for certain migratory game bird species are established by the Service annually as appropriate based on the biological status of these populations and published in the **Federal Register** as Federal limits. Tribes are encouraged to review each year the Federal limits to determine the list of migratory game bird species and species groups with authorized open seasons, and any special concerns regarding population status. Furthermore, annual review of the Federal limits for migratory game bird hunting seasons ensures that

Tribal regulations for nontribal members on reservation lands comply (as required by regulations) with opening and closing dates, season length, and daily bag and possession limits established by the Service.

As a result of the process explained above for authorizing seasonal migratory game bird hunting, information is requested from States annually on their proposed seasons. Therefore, this ICR incorporates the information requested from the States each year and other monitoring requirements for their seasons. We post all notices and rules electronically on the Service's website (<https://www.fws.gov/policy/frsystem/default.cfm>). State and Tribal governments are aware of this process that affords them the opportunity to provide comments on the information collection requirements identified in the Paperwork Reduction Act section of each rule.

The information identified below, necessary to establish annual migratory bird hunting seasons, is solicited annually from State and U.S. territory governments:

1. *Information Requested from States and U.S. Territories to Establish Annual Migratory Bird Hunting Seasons*—State and U.S. territory governments that wish to establish annual migratory game bird hunting seasons are required to provide the requested dates and other details for hunting seasons in their respective States or Territories. The information is provided to the Service in a nonform format, usually via letter or spreadsheet, in response to solicitations for the information sent to the State governments each year via an emailed letter.

2. *Details Needed from Tribal Governments*—This requirement is not applicable to Tribes that choose to observe the hunting regulations established by the State or States in which the reservation is located or independently establish special migratory bird hunting regulations in accordance with our regulations at 50 CFR 20.110. We will continue to consult with Tribes that wish to reach a mutual agreement (memorandum of understanding (MOU) or similar type of formal agreement) on conducting short-term (possibly several years) experimental hunting seasons using methods outside of the Federal hunting methods at § 20.21 for on-reservation and ceded lands hunting by Tribal members.

3. *Reports (50 CFR part 20)*—The following reports are requested from the States and are submitted either annually or every 3 years as explained in the following text.

a. *Atlantic Flyway Council*: Maryland, New Jersey, and New York—Two-tier hunting regulations study (phase 2) during 2027–28 through 2030–31 seasons per the terms of the study plan and Memorandum of Agreement among these States and the Service (Yearly updates and Final report).

b. *Central Flyway Council*: New Mexico and North Dakota—Two-tier hunting regulations study (phase 2) during 2027–28 through 2030–31 seasons per the terms of the study plan and Memorandum of Agreement among these States and the Service (Yearly updates and Final report).

c. *Mississippi Flyway Council*: Michigan—Two-tier hunting regulations study (phase 2) during 2027–28 through 2030–31 seasons per the terms of the study plan and Memorandum of Agreement among these States and the Service (Yearly updates and Final report).

d. *Pacific Flyway Council*: Arizona, Nevada, and Utah—Two-tier hunting regulations study (phase 2) during 2027–28 through 2030–31 seasons per the terms of the study plan and Memorandum of Agreement among these States and the Service (Yearly updates and Final report).

e. *Additional State-Specific Annual Reports*:

- Arizona—Sandhill crane season harvest and subspecies composition (3-year intervals).
- New Mexico—Sandhill crane season harvest and subspecies composition in Estancia Valley.
- Delaware, North Carolina and Virginia—Tundra swan season hunter participation and harvest.
- Montana (Central Flyway portion), North Dakota, and South Dakota—Tundra swan season hunter participation and harvest.
- Montana (Central Flyway portion) and South Dakota—Swan season hunter participation, harvest, species composition, and hunter compliance rates in providing species-determinant parts or bill measurements of harvested swans for species identification.
- Idaho, Montana (Pacific Flyway Portion), Utah, and Nevada—Swan season hunter participation, harvest, species composition, and hunter compliance rates in providing species-determinant parts or bill measurements of harvested swans for species identification.

Reports and monitoring are used for a variety of reasons. Some are used to monitor species composition of the harvest for those areas where species intermingling can confound harvest management and potential overharvest

of one species can be a management concern. Others are used to determine overall harvest for those species and/or areas that are not sampled well by our overall harvest surveys due to either the limited nature/area of the hunt or season or where the harvest needs to be closely monitored.

Experimental season reports are used to determine whether the experimental season is achieving its intended goals and objectives, without causing unintended harm to other species and ultimately whether the experimental season should proceed to operational status. Most experimental seasons are 3-year trials with yearly reports and a final report. Most of the other reports and monitoring are conducted either annually or at 3-year intervals.

4. *Requests for Consultation (Tribes/States)*—The 2023 regulations also may be applied to the establishment of migratory game bird hunting regulations for non-Tribal members on all lands within the reservations where Tribes have full wildlife-management authority over such hunting, or where the Tribes and affected States otherwise have reached agreement over hunting by non-Tribal members on non-Indian lands within the reservation. Tribes usually have the authority to regulate migratory game bird hunting by nonmembers on Indian-owned reservation lands.

The question of jurisdiction is more complex on reservations that include lands owned by non-Indians, especially when the surrounding States have established or intend to establish regulations governing migratory game bird hunting by non-Indians on these lands. In those cases, we encourage the Tribes and States to reach agreement on regulations that would apply throughout the reservations. If appropriate, we will consult with a Tribe and State with the aim of facilitating an accord. We also will consult jointly with Tribal and State officials in the affected States where Tribes may wish to establish special migratory game bird hunting regulations for Tribal members on ceded lands.

It is incumbent upon the Tribe and/or the State to request consultation. We will not presume to make a determination, without being advised by either a Tribe or a State, that any issue is or is not worthy of formal consultation. Tribal and State requests for consultation with the Service should be sent to the Service’s Assistant Director for the Migratory Bird Program. We note that our guidance on resolving issues of concern between Tribes and States on reservations and ceded lands is the same guidance we provided under the previous Tribal regulation process.

5. *Requests for Experimental Seasons (Tribes)*—We will continue to consult

with Tribes that wish to reach a mutual agreement (MOU or similar type of formal agreement) on conducting short-term (possibly several years) experimental hunting seasons using methods outside of the Federal hunting methods at § 20.21 for on-reservation and ceded lands hunting by Tribal members. The Tribal-member-only experimental hunting season would provide data and evaluation criteria specified in an agreement for consideration if a Tribe would like to make the additional hunting method operational. Tribes should send such requests for consultation to the Service’s Assistant Director for the Migratory Bird Program at least 9 months before the season or ceremony regarding hunting methods outside of the Federal regulations.

Title of Collection: Establishment of Annual Migratory Bird Hunting Seasons, 50 CFR part 20.
OMB Control Number: 1018–0171.
Form Number: None.
Type of Review: Extension of a currently approved collection.
Respondent’s Obligation: Required to obtain or retain a benefit.
Frequency of Collection: On occasion for new submissions, ongoing for recordkeeping requirements, and annually for reporting requirements.
Total Estimated Annual Nonhour Burden Cost: None.

Activity	Number of annual responses	Average time required per response (hours)	Total annual burden hours
Solicitation of Annual Season Selection Data	52	4	208
Reports from Experimental Hunting Seasons and Season Structure Changes	9	650	5,850
State-specific Reports (Yearly)	11	500	5,500
State-specific Reports (Every 3 Years)	1	500	500
Requests for Consultation	3	1	3
Requests for Experimental Seasons (Tribes)	3	4	12
Totals	79		12,073

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,
Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2026–21998 Filed 10–27–26; 8:45 am]
BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1439]

Certain Polyvinylidene Fluoride Resins, Notice of a Commission Determination To Review in Part a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined to review in part a final initial determination (“FID”) of the presiding administrative law judge (“ALJ”). The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Noah Priluck, Esq., Office of the General

Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3107. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on February 21, 2025, based on a complaint filed by Syensqo SA of Brussels, Belgium; Solvay Specialty Polymers, USA LLC of Alpharetta, Georgia; and Solvay Specialty Polymers Italy S.P.A. of Bollate, Italy (collectively, “Complainants”). 90 FR 10082–83 (Feb. 21, 2025). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain polyvinylidene fluoride resins by reason of infringement of claims 1–7, 10, and 12 of U.S. Patent No. 8,337,725 (“the ‘725 patent”). *Id.* The complaint further alleges that a domestic industry exists or is in the process of being established. *Id.* The Commission's notice of investigation named as respondents: (1) Inner Mongolia 3F Wanhao Fluorochemical Industry Co. Ltd. of Fengzhen, China (“3F”); (2) Zhejiang Juhua Co., Ltd. of Quzhou City, China (“Juhua”); (3) Zhejiang Fluorine Chemical New Material Co. Ltd. of Shaoxing, China; and Hubei Fluorine New Materials Co., Ltd. of Dongtan Village, China (collectively, “Fluorine”); and (4) Sinochem Lantian Co., Ltd. (“Sinochem”) of Hangzhou, China. *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

On July 14, 2025, the Commission amended the complaint and notice of investigation to include allegations asserting infringement of claims 8 and 9 of the ‘725 patent. Order No. 9 (June 23, 2025), *unreviewed by Comm’n Notice* (July 14, 2025), 90 FR 33394–95 (July 17, 2025). The Commission also amended the complaint and notice of investigation to change the name of two complainants from Solvay Specialty

Polymers, USA LLC to Syensqo Specialty Polymers, USA LLC, and Solvay Specialty Polymers Italy S.P.A. to Syensqo Specialty Polymers Italy S.P.A. to reflect corporate name changes. Order No. 19 (Nov. 19, 2025), *unreviewed by Comm’n Notice* (Dec. 9, 2025), 90 FR 57485 (Dec. 11, 2025).

The Commission previously terminated the investigation with respect to 3F. Order No. 8 (Mar. 28, 2025), *unreviewed by Comm’n Notice* (Apr. 21, 2025). The Commission also previously terminated the investigation with respect to claim 7 of the ‘725 patent. Order No. 24 (Dec. 4, 2024), *unreviewed by Comm’n Notice* (Jan. 5, 2026).

On September 29, 2025, the ALJ granted Respondents’ motion for summary determination of no importation or sale for importation as to Juhua, but not as to Fluorine or Sinochem. Order No. 16 (Sept. 29, 2025). On November 24, 2025, the ALJ granted Juhua’s motion to terminate itself from the investigation based on Order No. 16. Order No. 20 (Nov. 24, 2025).

From December 8–12, 2025, the ALJ held an evidentiary hearing involving Complainants and Respondents Fluorine and Sinochem.

On February 11, 2026, the Commission determined to review and, on review, reverse Order Nos. 16 and 20, thus reinstating Juhua as a party. Comm’n Notice (Feb. 11, 2026).

The ALJ held a supplementary evidentiary hearing on May 6, 2026.

On August 7, 2026, the ALJ issued the FID finding a violation of section 337 based on: (1) Complainants proving infringement of claims 1, 3, 6, 8, and 9 of the ‘725 patent with respect to all of the accused products; (2) Complainants proving importation of one accused product by respondent Fluorine but no importation of any other accused product;¹ (3) Respondents failing to prove any asserted claims invalid; (4) Complainants satisfying the technical prong of the domestic industry requirement with respect to claims 1, 3, and 6 of the ‘725 patent; and (5) Complainants proving that an economic domestic industry is in the process of being established as required by section 337(a)(2). The FID also includes the ALJ’s Recommended Determination should the Commission find a violation, recommending issuance of a limited exclusion order with a standard certification provision. The ALJ also

¹ Although the FID does not state so specifically, because the FID does not find importation by Juhua or Sinochem, the FID does not find a violation with respect to those respondents.

recommended that the Commission set a bond of 4.5 percent bond of the value of infringing imports during the period of Presidential review.

On August 21, 2026, Complainants and the named respondents filed petitions for review of the FID, with responses filed on August 31, 2026.

On September 8, 2026, Complainants filed a public interest submission pursuant to Commission Rule 210.50(a)(4)(i), 19 CFR 210.50(a)(4)(i). No submissions were filed in response to the Commission notice published in the **Federal Register** requesting submissions on the public interest from the public should the Commission find a section 337 violation. 91 FR 52711–12 (Aug. 14, 2026).

Having reviewed the record of the investigation, including the FID and the parties’ submissions to the ALJ and to the Commission, the Commission has determined to review the FID in part. Specifically, the Commission has determined to review the FID’s finding that the asserted claims of the ‘725 patent are not invalid for indefiniteness and for failure to satisfy the written description requirement. The Commission has also determined to review the FID’s findings as to whether Complainants have established importation or sale for importation with respect to Juhua, Sinochem, and Fluorine. The Commission has determined not to review the remainder of the FID’s findings.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

1. Explain whether the term “sale for importation” requires knowledge (actual or constructive) of the importation. Did Congress intend to prevent the Commission from excluding infringing imports in the absence of such knowledge? Provide support with reference to the statute (including the provisions regarding violation and remedy establishing the Commission’s statutory authority over the imported articles), the legislative history, and/or applicable precedent. If some kind of knowledge is required, what evidence should be considered in determining whether the sale for importation is satisfied?

2. Address whether the asserted claims of the ‘725 patent are invalid for indefiniteness under 35 U.S.C. 112 taking into account the parties’ electrode-based and acetone-based arguments, and, in particular whether the FID correctly focuses on the global maximum rate of change, rather than the

local maximum rates of change in analyzing the relevant titrations.

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. See Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainants are also requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainants are further requested to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. All initial written submissions, from the parties and/or third parties/interested government agencies, and proposed remedial orders from the parties must be filed no later than the close of business on November 6, 2026. All reply submissions must be filed no later than the close of business on November 13, 2026. Opening submissions from the parties are limited to 25 pages. Reply submissions from the parties are limited to 15 pages. All submissions from third parties and/or interested government agencies are limited to 10 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (Inv. No. 337-TA-1439) in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party

wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on October 23, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 23, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026-21942 Filed 10-27-26; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1514]

Certain Adjustable Child Carriers and Components Thereof; Notice of a Commission Determination Not To Review an Initial Determination Granting Complainant's Motion for Leave To Amend the Complaint and Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined not to review an initial determination (“ID”) (Order No. 15) of the presiding administrative law judge (“ALJ”), granting Complainant The Ergo Baby Carrier, Inc.’s (“Ergobaby’s”) motion for leave to amend the complaint and notice of institution of investigation (“NOI”) to add a respondent.

FOR FURTHER INFORMATION CONTACT:

Joelle Justus, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2593. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 27, 2026, based on a complaint filed by Ergobaby of Torrance, California. 91 FR 46944–45 (July 27, 2026). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain adjustable child carriers and components thereof by reason of infringement of claims 1–3, 5, 6, 12, 16, and 17 of U.S. Patent No. 10,426,275 and claims 1, 6–11, 17, 18, and 22–25 of U.S. Patent No. 12,016,470. *Id.* at 46945. The Commission’s notice of investigation named the following respondents: Mabe, LLC of Shelley, Idaho; Quanzhou Baby Nice Infant and Child Products Co., Ltd. of Quanzhou City, China; Xiamen Funwhale Technology LLC and Xiamen New Baby Products Co., Ltd. (“Xiamen NBB”) of Xiamen City, China; Koi Trading Services of Diamond Bar, California; Portier USA, LLC of Sheridan, Wyoming; Ava + Oliver, LLC of Honolulu, Hawaii; Artipoppe B.V. of Lexmond, The Netherlands; Bugaboo Xiamen Industrial Co. Ltd. of Xiamen, China; Bugaboo International B.V. of Amsterdam, The Netherlands; and Bugaboo North America, Inc. of New York, New York. *Id.* The complaint

further alleges that a domestic industry exists. *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *See id.*

On September 16, 2023, Ergobaby filed a motion for leave to amend the complaint and NOI to add Xiamen Danke Health Technology Co., Ltd., a/k/a xiamen danke jiankang keji you xian gong si (“Xiamen Danke”) of Xiamen, China as a respondent. None of the participating respondents opposed the motion. *See* Order No. 15 at 1 (Sept. 24, 2026).

On September 24, 2026, the ALJ issued the subject ID (Order No. 15) granting Ergobaby’s motion. The ID finds good cause to amend the complaint and NOI because Ergobaby did not know of Xiamen Danke’s role as the manufacturer of certain accused products until Xiamen NBB disclosed that information in its response to the complaint and NOI. Order No. 15 at 2. The ID notes that Ergobaby filed its motion three weeks after learning of Xiamen Danke and four business days after receiving additional information regarding Xiamen Danke in Xiamen NBB’s discovery responses. *Id.* The ID further finds that Ergobaby’s proposed amendment would not prejudice the public interest or the rights of the parties to the investigation because the products manufactured by Xiamen Danke are already part of the investigation and the investigation is in the early stages. *Id.* at 3. No petitions for review of the subject ID were filed.

The Commission has determined not to review the subject ID. Xiamen Danke is added as a respondent in this investigation.

The Commission vote for this determination took place on October 26, 2026.

The authority for the Commission’s determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission’s Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 26, 2026.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2026–21981 Filed 10–27–26; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB 1140–0074]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Revising a Previously Approved Collection; Explosives Responsible Person Questionnaire (RPQ)—ATF Form 5400.27

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 28, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection, especially on the estimated public burden or associated response time, to Shawn Stevens, Federal Explosives Licensing Center, by email to FELC@atf.gov, or by mail to Federal Explosives Licensing Center (ATF–FELC); 244 Needy Road; Martinsburg, WV 25405. Identify comments by the OMB control number 1140–0074. 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 Shawn Stevens, Federal Explosives Licensing Center, by email at FELC@atf.gov, or by telephone at 877–283–3352. 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, Enterprise Portfolio Management; 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: Title XI of the Organized Crime Control Act of 1970 (the Act) and its implementing regulations at 27 CFR part 555 require that persons who want to engage in the business of manufacturing, importing, or dealing in explosives, or using them, must file an application with ATF for an explosives license/permit. This requirement also mandates that the applicant include

specific information about responsible persons (RPs) and other employees who are authorized to handle explosives in the course of their duties (employee possessors, EPs). RPs are persons who have the power to direct a federal explosives licensee/permittee’s management and policies pertaining to explosive materials. Further, 18 U.S.C. 843(h) requires ATF to conduct background checks on the applicant and any RPs and EPs, and section 843(a) requires that RPs submit fingerprints and a photograph with the form. These requirements help ensure compliance with the provisions of 18 U.S.C. 842(i), which prohibits certain persons from possessing explosive materials. This information collection covers the requirement to submit information on RPs. All persons holding ATF explosives licenses/permits must report to ATF identifying information about their RPs and any subsequent changes to their RPs. ATF’s regulations establish that applicants must use ATF Form 5400.27, Explosives Responsible Person Questionnaire (RPQ) for this purpose. Doing so helps ensure that respondents provide all the necessary information to conduct the RP background checks and ensure they are not prohibited from operations involving explosives.

Type of information collection: revising a previously approved collection.

Title of the form/collection: Explosives Responsible Person Questionnaire (RPQ).
Agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number: ATF Form 5400.27. *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: business or other for-profit, individuals or households. *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: There are an estimated 7,509 respondents associated with this collection per year, and it will take each respondent an average of approximately 20 minutes (0.33 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 2,478 hours, which is equal to 7,509 (total respondents) * 1 (# of responses per respondent) * 0.33 hours.
Estimate of the total annual other cost burden associated with the collection, if applicable: \$187,750 for fingerprints at a cost of \$50 per respondent.

ESTIMATED TOTAL HOURLY BURDEN

Activity	Number of respondents	Frequency	Total annual responses	Time per response (hours)	Total annual burden (hours)
Completing application	7,509	1	7,509	0.33	2,478

Revisions to This Information Collection

As part of this ICR renewal, ATF is making a minor change to the title of the IC to align with the way ATF and industry have been referring to it, from “List of Responsible Persons” to “Explosives Responsible Person Questionnaire (RPQ).” In addition, ATF is changing the form’s number from 5400.13A/5400.16 to ATF Form 5400.27. The form no longer needs a reference to a long-rescinded merged form, and under ATF’s updated numbering structure, numbering it 5400.27 allows it to be numerically next to the Employee Possessor Questionnaire. These two forms are normally submitted together as part of an application package. ATF has also updated the digitally fillable and signable form to include an email address and instructions for submitting

electronically, and made minor plain writing edits throughout. Finally, the number of respondents has decreased during the past three years, from 11,875 in 2023 to 7,509 now, a decrease of 4,366 respondents. The decrease in respondents resulted in a corresponding decrease in the total annual burden hours, from 3,958 to 2,478 a decrease of 1,480 hours.

October 26, 2026.
Darwin Arceo,
Department Clearance Officer for PRA, U.S. Department of Justice.
[FR Doc. 2026–22010 Filed 10–27–26; 8:45 am]
BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE
[OMB 1140–0070]
Agency Information Collection Activities; Proposed Collection; Comments Requested; Revising a Previously Approved Collection; Title—Application for Explosives License/Permit—ATF Form 5400.13
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 28, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection, especially on the estimated public burden or associated response time, to Shawn Stevens, by email to FELC@atf.gov, or by mail to Federal Explosives Licensing Center (ATF-FELC); 244 Needy Road, Martinsburg, WV 25405. Identify comments by the OMB control number 1140-0070. 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 Shawn Stevens, FELC, either by mail at Federal Explosives Licensing Center (ATF-FELC); 244 Needy Road, Martinsburg, WV 25405, by email at FELC@atf.gov, or by telephone at 877.283.3352. 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, Enterprise Portfolio Management; 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: 18 U.S.C. chapter 40 requires any person engaged in the business of manufacturing, importing, or dealing in explosive materials to first obtain a license. 18 U.S.C. 842(a)(1). The statute also requires all persons who wish to obtain explosives, even for limited use, to obtain a federal explosives license or a permit (to use explosives, rather than engage in the business). This also includes all persons who wish to ship, transport, receive, or possess explosive materials. 18 U.S.C. 843. ATF has prescribed ATF Form 5400.13, Application for Explosives License/Permit, as the means by which persons may apply for a federal explosives license or permit (FEL/P). Each person (individual, partnership, corporation, or association) applying for a FEL/P must submit ATF Form 5400.13. ATF uses the information on the application to determine if the

applicant is qualified to be an explosives licensee/permittee under the statute. Part of the process of determining whether a person qualifies to be a licensee/permittee includes a background check to ascertain whether the person is prohibited from possessing or otherwise using explosive materials.

Type of information collection: revising a previously approved collection.

Title of the form/collection: Application for Explosives License/Permit.

Agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number: ATF Form 5400.13. *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: business or other for-profit; individuals or households. *Obligation to respond:* mandatory per 27 CFR 555.41 and 555.45, required to obtain a benefit.

Estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: There are an estimated 927 respondents associated with this collection per year, and it will take each respondent an average of approximately 1.5 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 1,390.5 hours, which is equal to 927 (total respondents) * 1 (# of responses per respondent) * 1.5 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	927	1	927	1.5	1,390.5

Revisions to This Information Collection

As part of this ICR renewal, ATF has updated Form 5400.13 to reflect the new government payment method through pay.gov (required by executive order) and to include instructions and an email address for submitting the digitally fillable and signable form to ATF by email. ATF is also making a minor edit to the title, from "Application for

Federal Explosives License or Permit" to "Application for Explosives License/Permit" for plain writing and brevity. In addition, ATF is changing the form number from 5400.13/5400.16 to 5400.13. There is no longer a need to retain the reference to a long-canceled merged form. Finally, there has been a decrease in the number of respondents to this IC, from 10,200 during the last renewal in 2023, to 927, a decrease of

9,273 respondents. This resulted in a corresponding decrease to the number of burden hours, from 15,300 in 2023 to 1,390.5 in 2026, a decrease 13,909.5 hours.

Dated: October 26, 2026.

Darwin Arceo,
Department Clearance Officer for PRA, U.S.
Department of Justice.

[FR Doc. 2026-22009 Filed 10-27-26; 8:45 am]

BILLING CODE 4410-FY-P

DEPARTMENT OF JUSTICE

[OMB 1140–0028]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Revising a Previously Approved Collection; Title—Explosives Licensee/Permittee Inventories

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 28, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection, especially on the estimated public burden or associated response time, to Jonathan Fulcher, Explosives Industry Programs Branch, by email to eipb-informationcollection@atf.gov, or by mail to Explosives Industry Programs Branch; Bureau of Alcohol, Tobacco, Firearms, and Explosives; 3750 Corporal Road; Huntsville, AL 35898. Identify comments by the OMB control number 1140–0028.

FOR FURTHER INFORMATION CONTACT: If you have questions or need a copy of the proposed information collection instrument with instructions or additional information, contact Jonathan Fulcher, EIPB, by email at eipb-informationcollection@atf.gov, or by telephone at 202.648.7120. 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, Enterprise Portfolio Management; 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: Federal explosives licensees/permittees (FEL/Ps) play a significant role in preserving public safety, including preventing crimes involving explosives, such as domestic or foreign terrorist acts. ATF's regulation at 27 CFR 555.121 provides that FEL/Ps must keep records pertaining to explosive materials in permanent form (e.g., commercial invoices, record books) and in the manner required in 27 CFR part 555, subpart G. These records are required under 18 U.S.C. 842 (f),(g),(j), (k), 843(f), and 847, and are established in the manner set forth in 27 CFR 555.121, 555.122, 555.123, 555.124, 555.125, and 555.127. As part of their record-keeping requirements, FEL/Ps must take a physical inventory at least once during each year. FEL/Ps must also take special physical inventories when they are: (1) commencing business, (2) changing premises, (3) discontinuing business, or, (4) requested to do so by the ATF Director, Industry Operations. If one of

these special inventories occurs, the FEL/P is not required to take an additional inventory that same year. The inventory aids FEL/Ps in accounting for all their explosives material and reconciling cost, sales, and use records with inventory. It also establishes initial figures from which an audit trail can be developed by ATF field officers during a compliance inspection or criminal investigation. Specifically, ATF uses inventory figures to reconcile the physical inventory on hand and the book inventory the FEL/P maintains. These reconciliations are conducted on an ongoing basis, to determine whether any unlawful diversions of explosive materials have occurred, especially those arising through theft by persons not affiliated with the FEL/P.

Type of information collection: revising a previously approved collection.

Title of the form/collection: Explosives Licensee/Permittee Inventories.

Agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number: no form. 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: business, other for-profit. Obligation to respond: mandatory per 18 U.S.C. 842 (f),(g),(j), (k), 843(f), and 847.

Estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: There are an estimated 9,130 respondents associated with this collection per year, and it will take each respondent an average of approximately two 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 18,260 hours, which is equal to 9,130 (total respondents) * 1 (# of responses per respondent) * 2 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	9,130	1	9,130	2	18,260

Revisions to This Information Collection

As part of this ICR renewal, ATF is making no revisions to this information collection, OMB 1140–0028. However, ATF has revised the title of the ICR from “Inventories: Licensed Explosives Importers, Manufacturers, Dealers, and Permittees” to “Explosives Licensee/Permittee Inventories” for plain writing purposes and to make it shorter. In addition, the number of annual respondents has decreased since the last renewal—from 9,219 in 2023 to 9,130 in 2026—a drop of 89 respondents. This resulted in a corresponding decrease in the total annual burden hours, from 18,438 to 18,260, a difference of 178 hours.

Dated: October 26, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–22013 Filed 10–27–26; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB 1140–0072]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Revising a Previously Approved Collection Explosives Employee Possessor Questionnaire (EPQ)—ATF Form 5400.28

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 28, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection, especially on the estimated public burden or associated response time, to Shawn Stevens, Federal Explosives Licensing Center, by email to FELC@atf.gov, or by mail to Federal Explosives Licensing Center (ATF–FELC); 244 Needy Road; Martinsburg, WV 25405. Identify

comments by the OMB control number 1140–0072. 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 Shawn Stevens, Federal Explosives Licensing Center, by email at FELC@atf.gov, or by telephone at 877.283.3352. 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, Enterprise Portfolio Management; 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: Title XI of the Organized Crime Control Act of 1970 (the Act) and its implementing regulations at 27 CFR part 555 require that persons who want to engage in the business of manufacturing, importing, or dealing in explosives, or using them, must file an application with ATF for an explosives license/permit. This requirement also mandates that the applicant include

specific information about responsible persons (RPs) and other employees who are authorized to handle explosives in the course of their duties (employee possessors, EPs). Further, 18 U.S.C. 843(h) requires ATF to conduct background checks on the applicant and any RPs and EPs. These requirements help ensure compliance with the provisions of 18 U.S.C. 842(i), which prohibits certain persons from possessing explosive materials. This information collection covers the requirement to submit information on EPs. All persons holding ATF explosives licenses/permits must report to ATF identifying information about their EPs and any subsequent changes to their EPs. ATF’s regulations establish that applicants must use ATF Form 5400.28, Explosives Employee Possessor Questionnaire (EPQ) for this purpose. Doing so helps ensure that respondents provide all the necessary information to conduct the EP background checks and ensure they are not prohibited from operations involving explosives.

Type of information collection: revising a previously approved collection.

Title of the form/collection: Explosives Employee Possessor Questionnaire (EPQ).

Agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number: ATF Form 5400.28. 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: business or other for-profit, individuals or households. **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: There are an estimated 80,661 respondents associated with this collection per year, and it will take each respondent an average of approximately 20 minutes (0.33 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 26,860 hours, which is equal to 80,661 (total respondents) * 1 (# of responses per respondent) * 0.33 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	80,661	1	80,661	0.33	26,860

Revisions to This Information Collection

As part of this ICR renewal, ATF is making a minor change to the title of the IC to align with the way ATF and industry have been referring to it, from “List of Responsible Persons” to “Explosives Responsible Person Questionnaire (RPQ).” ATF has also updated the digitally fillable and signable form to include an email address and instructions for submitting electronically, and made minor plain writing edits throughout. Finally, the number of respondents has decreased during the past three years, from 83,125 in 2023 to 80,661 now, a decrease of 2,464 respondents. The decrease in respondents resulted in a corresponding decrease in the total annual burden hours, from 27,708 to 26,860, a decrease of 848 hours.

Dated: October 26, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–22008 Filed 10–27–26; 8:45 am]

BILLING CODE 4410-FY-P

DEPARTMENT OF JUSTICE

[OMB 1140–0098]

Agency Information Collection Activities; Proposed Collection; Comments Requested; Revising a Previously Approved Collection Title—Prevent All Cigarette Trafficking (PACT) Act Registration Form—ATF Form 5070.1

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 28, 2026.

ADDRESSES: Submit written comments and recommendations for this information collection, especially on the estimated public burden or associated response time, to Moliki Alexander, National Firearms Trafficking Center, by email to ATEBmailbox@atf.gov, or by mail to National Firearms Trafficking Center, Mailstop 8.E–406; 99 New York Ave NE; Washington, DC 20226. Identify comments by the OMB control number 1140–0098. 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 Moliki Alexander, either by mail at National Firearms Trafficking Center; 99 New York Ave NE; Washington, DC 20226, by email at ATEBmailbox@atf.gov, or by telephone at 202–648–7720. 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, Enterprise Portfolio Management; 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: The Prevent All Cigarette Trafficking Act of 2009 (15 U.S.C. 375–378, 18 U.S.C. 1716E) requires any person who sells, transfers, or ships for profit cigarettes or smokeless tobacco in interstate commerce to register with the Attorney General of the United States (delegated to ATF) and the state tax administrators of the states to which the person ships the tobacco products or in which the person advertises or offers them. Persons who sell these products must report sales into the jurisdictions, and if they engage in delivery sales, they must comply with state and local tax laws. In 2021, electronic nicotine delivery systems (ENDS) became subject to regulation under the PACT Act through the Preventing Online Sales of E-Cigarettes to Children Act. This act expanded the definition of a ‘cigarette’ within the PACT Act to include “any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device.” Respondents use ATF Form 5070.1, Prevent All Cigarette Trafficking (PACT) Act Registration Form, to comply with the federal registration requirements. ATF uses the collected information to register applicants and to create and maintain a PACT Act registration database for registrants and a database for the unregistered/non-compliant delivery sellers. The non-compliant list is available to the attorneys general and tax administrators of each state, common carriers, and other persons the Attorney General deems appropriate.

Type of information collection: revising a previously approved collection.

Title of the form/collection: Prevent All Cigarette Trafficking (PACT) Act Registration Form.

Agency form number, if any, and the applicable component of the Department sponsoring the collection: Form number: ATF Form 5070.1.

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: business or other for-profit. *Obligation to respond:* mandatory per 15 U.S.C. 375–378, 18 U.S.C. 1716E.

Estimate of the total number of respondents and the amount of time

estimated for an average respondent to respond: There are an estimated 1,396 respondents associated with this collection per year, and it takes each respondent an average of approximately 30 minutes (0.5 hours) per response to complete the form.

Estimate of the total annual burden (in hours) associated with the collection: The estimated annual public burden

associated with this collection is 698 hours, which is equal to 1,396 (total respondents) * 1 (# of responses per respondent) * 0.5 hours.

Estimate of the total annual other cost burden associated with the collection, if applicable: 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	1,396	1	1,396	0.5	698

Revisions to This Information Collection

As part of this ICR renewal, ATF is making no program changes affecting this information collection, OMB 1140–0098. However, the number of registrants have increased (596 persons) since the last renewal in 2023, from 800 respondents to 1,396. In addition, the registration forms have been made electronically downloadable, fillable, signable, and submittable by email. This has resulted in a decrease in the amount of time it takes to complete the form, from 1 hour to 30 minutes. The combined increase in respondents and decrease in time has resulted in a net decrease in burden hours, from 800 during the last renewal to 698 in 2026. ATF has also made minor plain writing edits to the form, and has merged the continuation sheet, formerly Form 5070.1A, into Form 5070.1. Because this is a fully electronic form, there is no longer a need for a separate continuation sheet.

Dated: October 26, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–22012 Filed 10–27–26; 8:45 am]

BILLING CODE 4410–FY–P

Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before November 27, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Nora Hernandez by telephone at 202–693–8633, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: The Wage and Hour Division (WHD) of the Department of Labor (DOL) administers the Employee Polygraph Protection Act of 1988 (EPPA), 29 U.S.C. 2001 *et seq.* The EPPA prohibits most private employers from using any lie detector tests either for pre-employment screening or during employment. The Act contains an exemption applicable to federal, state, and local government employers. The EPPA also contains several limited exemptions authorizing polygraph tests under certain conditions, including testing (1) by the federal government of experts, consultants, or employees of Federal contractors engaged in national security intelligence or counterintelligence functions; (2) of employees the employer reasonably suspects of involvement in a workplace incident resulting in economic loss or injury to the employer’s business; (3) of some

prospective employees of private armored cars, security alarm and security guard firms; and (4) of some current and prospective employees of certain firms authorized to manufacture, distribute, or dispense controlled substances. WHD may assess civil money penalties against employers who violate any EPPA provision. This amount increases annually due to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 27, 2026 (91 FR 46970).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency’s estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology. To help ensure appropriate consideration, comments should reference OMB Control Number 1235–0005.

This information collection is subject to PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Employee Polygraph Protection Act

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Wage and Hour Division (WHD)-sponsored information collection request (ICR) to the Office of

law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review. The Department of Labor seeks approval for the revision of this information collection to ensure effective administration of the laws administered by the WHD.

Agency: DOL–WHD.

Title of Collection: Employee Polygraph Protection Act.

OMB Control Number: 1235–0005.

Affected Public: Private Sector: Businesses or other for-profits.

Total Estimated Number of Respondents: 164,000.

Total Estimated Number of Responses: 757,400.

Total Estimated Annual Time Burden: 68,739 hours.

Total Estimated Annual Other Costs Burden: \$0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nora Hernandez,

PRA Department Clearance Officer.

[FR Doc. 2026–22006 Filed 10–27–26; 8:45 am]

BILLING CODE 4510–27–P

NATIONAL CREDIT UNION ADMINISTRATION

[NCUA–2026–2146]

NCUA Draft 2027–2028 Budget

AGENCY: National Credit Union Administration (NCUA)

ACTION: Notice.

SUMMARY: NCUA’s draft “detailed business-type budget” is being made available for public review as required by federal statute. The proposed resources will finance the agency’s annual operations and capital projects, both of which are necessary for the agency to accomplish its mission of enabling access to financial services by facilitating safe, sound, and resilient credit unions. Comment instructions are included in the **SUPPLEMENTARY INFORMATION** section.

DATES: Requests to deliver an in-person statement at the November 17, 2026, budget hearing must be received on or before November 6, 2026. Written

statements for those scheduled to appear at the budget hearing must be received on or before 12 noon Eastern, November 12, 2026.

Written comments may be submitted by November 30, 2026.

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

- *In-person presentation at public budget hearing:* submit requests to deliver a statement to BudgetHearing@ncua.gov by November 6, 2026. Include your name, title, affiliation, mailing address, email address, and telephone number. The NCUA Board Secretary will inform you if you have been approved to make a presentation. In order to present at the hearing, you must submit a statement. Your statement must be submitted to BudgetHearing@ncua.gov by 12 noon Eastern, November 12, 2026. Your presentation must be delivered in person at the public budget hearing. You will be allotted five minutes to deliver your remarks.

- *Written comments without an in-person presentation:* submit written comments by November 30, 2026, through the Federal eRulemaking Portal: <https://www.regulations.gov>. The docket number is NCUA–2026–2146. Follow the instructions for submitting comments.

Copies of NCUA’s draft 2027–2028 budget and associated materials are also available on NCUA’s website at <https://www.ncua.gov/About/Pages/budget-strategic-planning/supplementary-materials.aspx>.

FOR FURTHER INFORMATION CONTACT:

Melissa M. Lowden, Acting Chief Financial Officer, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, or telephone: (703) 518–1182.

SUPPLEMENTARY INFORMATION: The following itemized list details the sections in this Notice made available for public review:

- I. Introduction
- II. NCUA’s Budget in Brief
- III. Key Themes of the Proposed 2027–2028 Budget
- IV. Operating Budget
- V. Capital Budget
- VI. Share Insurance Fund Administrative Budget
- VII. Financing NCUA’s Programs
- VIII. Appendix: Supplemental Budget Information

Section 212 of the Economic Growth, Regulatory Relief, and Consumer Protection Act amended 12 U.S.C. 1789(b)(1)(A) to require the NCUA Board (Board) to “on an annual basis and prior to the submission of the detailed business-type budget make

publicly available and publish in the **Federal Register** a draft of the detailed business-type budget.” Although 12 U.S.C. 1789(b)(1)(A) requires publication of a “business-type budget” only for the agency operations arising under the Federal Credit Union Act’s subchapter on insurance activities, in the interest of transparency the Board is providing NCUA’s entire draft budget for 2027–2028 in this Notice.

The draft budget details the resources required to support NCUA’s mission. The draft budget includes personnel and dollar estimates for three major budget components: (1) the Operating Budget; (2) the Capital Budget; and (3) the Share Insurance Fund Administrative Budget. The resources proposed in the draft budget are to carry out the agency’s operations in 2027 and 2028. This document is a draft, staff-level budget proposal made available to the NCUA Board and the public for their consideration and comment. The NCUA Board directed NCUA’s Executive Director to develop the draft budget under delegated authority. The draft budget may change based on public comments, Board decisions, and staff’s ongoing consideration of estimates and programs that impact the budget.

NCUA’s Chief Financial Officer will present the draft budget at a hearing open to the public on Tuesday, November 17, 2026, at 10:00 a.m. Eastern at NCUA’s headquarters, 1775 Duke Street, Alexandria, Virginia 22314. Interested parties unable to attend in person may visit the agency’s homepage (<https://www.ncua.gov/>) to access the provided webcast link.

If you wish to participate in the hearing and deliver a statement, you must email a request to BudgetHearing@ncua.gov by November 6, 2026. Your request must include your name, title, affiliation, mailing address, email address, and telephone number. Statements must be delivered in person at the hearing. NCUA will work to accommodate as many public statements as possible. The Board Secretary will inform you if you have been approved to make a presentation and you will be allotted five minutes during the budget hearing to deliver your remarks. A written copy of your statement must be delivered to the Board Secretary by email by 12 noon Eastern, November 12, 2026. In addition to delivering their remarks at the budget hearing, registered presenters will be provided the opportunity to ask questions of NCUA staff about the draft budget. The initial round of questions will be limited to five minutes per presenter, and one subsequent round of questions, limited to five minutes per

presenter, may be permitted by the Chairman if time allows.

Written comments on the draft budget will be accepted by November 30, 2026, through the Federal eRulemaking Portal: <https://www.regulations.gov>. The docket number is NCUA–2026–2146.

Commenters should follow the portal instructions for submitting comments.

All comments should provide specific, actionable recommendations about the draft budget rather than general remarks. NCUA's Board will review and consider any comments from the public before approving NCUA's 2027–2028 budget.

By the National Credit Union Administration Board on October 23, 2026.

Melane Conyers-Ausbrooks,

Secretary of the Board.

I. Introduction

About the National Credit Union Administration

Created by the U.S. Congress in 1970, the National Credit Union Administration (NCUA) is the federal agency that insures deposits at federally insured credit unions, protects the members who own credit unions, and charters and regulates federal credit unions.

NCUA's mission is to enable access to financial services by facilitating safe, sound, and resilient credit unions.

The agency operates its headquarters in Alexandria, Virginia; its Asset Management and Assistance Center (AMAC) in Austin, Texas, which liquidates credit unions and recovers assets; and three regional offices, which carry out the agency's supervision and examination program.

Backed by the full faith and credit of the United States, the National Credit Union Share Insurance Fund (Share Insurance Fund) provides up to \$250,000 of federal share insurance to millions of account holders in all federal credit unions and most state-chartered credit unions.

As of June 30, 2026, NCUA regulates and supervises 4,214 federally insured credit unions, which have approximately 146 million members and \$2.5 trillion in assets.¹

Statutory Authority

Pursuant to the Federal Credit Union Act (FCU Act), the NCUA Board (the Board) determines the resources needed for carrying out NCUA's responsibilities under the Act.² The Board is authorized to expend such funds and perform such other functions or acts as it deems necessary or appropriate, according to the rules, regulations, or policies it establishes.³

The FCU Act authorizes two primary sources to fund NCUA: (1) Requisitions from the Share Insurance Fund “for such administrative and other expenses incurred in carrying out the purposes of [Title II of the Act] as [the Board] may determine to be proper” and (2) “fees and assessments (including income earned on insurance deposits) levied on insured credit unions under [the Act].”⁴

Pursuant to its authority to use the Share Insurance Fund to carry out its insurance-related responsibilities, the Board approved an Overhead Transfer Rate (OTR) methodology and authorized the Office of the Chief Financial Officer to transfer resources from the Share Insurance Fund to the Operating Fund to account for insurance-related expenses.⁵

In December 2023, the Board approved and published in the **Federal Register** the current federal credit union annual operating fee methodology, which is the basis for how the operating fee is calculated.⁶ The Board delegated authority to the Chief Financial Officer to calculate the annual operating fee for federal credit unions and to set the fee schedule as calculated using the approved method.

Pursuant to the FCU Act, NCUA deposits fees collected in the agency's Operating Fund at the Treasury of the United States, and NCUA uses those fees to defray the cost of carrying out the agency's operations, including

examining and supervising federal credit unions.⁷

NCUA's Annual Budget Process

The FCU Act requires NCUA to publish an annual draft budget in the **Federal Register** for public comment and hold a public hearing on the budget.⁸ NCUA stands out as the only Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA) agency that releases a detailed draft budget and solicits public comments on it.

NCUA develops a two-year draft budget by identifying the necessary resources, including supporting justifications, to achieve the agency's mission, goals, requirements, and objectives. This effort includes a field-level review of every federally insured credit union to estimate the workload to examine and supervise the credit union in the forthcoming year, which is translated into the cost of the staff and associated expenses for such functions. In addition to this workload analysis, each NCUA office reviews its fixed and recurring expenses, including:

- Employee travel.
- Rental payments for leased property.
- Operations and maintenance for owned facilities or equipment.
- Supplies.
- Telecommunications services.
- Major capital investments.
- Other administrative and contracted services costs.

Before arriving at the final budget, the NCUA Board reviews any comments from the public and evaluates other considerations. Once the budget is approved, the OTR and federal credit union annual operating fee rates are set for the first year of the two-year budget.

II. NCUA's Budget in Brief

Proposed 2027 and 2028 Budgets

NCUA's 2027–2028 draft budget includes three separate budgets: the Operating Budget, the Capital Budget, and the Share Insurance Fund Administrative Expenses Budget.⁹

⁷ See 12 U.S.C. 1755(d).

⁸ See 12 U.S.C. 1789(b).

⁹ Budget information presented in this document excludes funding for the Central Liquidity Facility (CLF), which has its own budget that is reviewed and decided upon separately by the CLF Board.

² See 12 United States Code (U.S.C.) 1752a.

³ See 12 U.S.C. 1766(i)(2).

⁴ See 12 U.S.C. 1783(a); 12 U.S.C. 1766(j)(3). An annual operating fee is paid by federal credit unions pursuant to 12 U.S.C. 1755. NCUA is not funded through the annual Congressional appropriations process.

⁵ See 12 U.S.C. 1783(a).

⁶ See www.federalregister.gov/documents/2023/12/26/2023-28303/national-credit-union-administration-operating-fee-schedule-methodology.

¹ Source: NCUA quarterly call report data, second quarter 2026.

2027 – 2028 NCUA BUDGET RESOURCES							
Budget	2026 Board- Approved Budget	2027 Requested Budget	Change (2026-2027)	Percent Change (2026-2027)	2028 Requested Budget	Change (2027-2028)	Percent Change (2027- 2028)
Operating Budget	\$ 288,711,000	\$ 312,416,000	\$ 23,705,000	8.2%	\$ 331,000,000	\$ 18,584,000	5.9%
Capital Budget	\$ 24,128,000	\$ 7,924,000	\$ -16,204,000	-67.2%	\$ 8,000,000	\$ 76,000	1.0%
Share Insurance Fund Admin. Budget	\$ 3,311,000	\$ 5,054,000	\$ 1,743,000	52.6%	\$ 5,156,000	\$ 102,000	2.0%
Total	\$ 316,150,000	\$ 325,394,000	\$ 9,244,000	2.9%	\$ 344,156,000	\$ 18,762,000	5.8%
Positions	967	972	5	0.5%	972	---	0.0%

Note: Total positions shown in the table above exclude those funded by the Central

Liquidity Facility.

Combined, these three proposed 2027 budgets total \$325.4 million, an increase of 2.9 percent compared to the 2026 Board-approved budget, and consistent with the 2027 funding level approved by the NCUA Board as part of the 2026–2027 budget.

There are three main factors contributing to the draft 2027 budget growth compared to 2026:

- Growth in employee compensation budgets, reflecting the pay raise terms in the agency's compensation agreement with its employee union, inflationary adjustments for employee benefits, and five proposed additional positions required to meet emerging needs related to new legislation as well as the Administration's priorities.

- An increase in contracted services budgets, resulting from inflationary cost increases, cybersecurity investments, and because the agency projects \$10.0 million less in offsetting, prior-year surpluses than 2026.

- An increase in the Share Insurance Fund Administrative Expenses Budget. NCUA used the proceeds from the sale of its Austin office building to offset the 2026 budget, which was a one-time offset.

These increases are partially offset by a comparative decrease to NCUA's Capital Budget for 2027. The 2026 Capital Budget included \$16 million for reorganization-related investments in systems and process improvements that align with government efficiency goals and other Administration priorities. The 2027 Capital Budget does not include any additional funding for reorganization-related investments or projects.

Proposed 2028 Budget: \$344.2 Million

The 2028 combined total for the three proposed budgets is \$344.2 million,

which is 5.8 percent higher than the proposed 2027 combined total.

For planning purposes, the 2028 draft budget projects the same rate of compensation growth as in 2027, and 3.0 percent budgetary growth in all non-compensation spending categories plus certain discrete adjustments in cases where project cost growth is expected to exceed 3.0 percent. The remaining growth results from a lower estimate of prior-year surpluses offsetting the 2028 budget compared to the surplus used in 2027.

While the agency presents a two-year draft budget for planning purposes, the Board's practice has been to revisit each year's budget before that budget year begins.

III. Key Themes of the Proposed 2027–2028 Budget

NCUA Reorganization

Since the start of its Voluntary Separation Program in 2025, which resulted in a 23 percent reduction to its staffing, NCUA has been developing reorganization plans to build more productive, efficient agency operations. Throughout 2025 and 2026, NCUA has increased its operational efficiency and improved service delivery. The agency has been removing unnecessary and burdensome regulations, streamlining its business processes, and identifying technological improvements, and will continue to do so in 2027 and 2028.

The draft 2027–2028 budget supports NCUA's strategic restructuring plans. The agency's reorganization process is actively underway and targeted for completion by December 2027. The agency's reorganization efforts focus on prioritizing NCUA's statutory authorities and its most critical work, reducing and consolidating business units with like functions, achieving a

higher supervisor to employee ratio, and leveraging technology to increase staff efficiency.

Technology Modernization: Enhanced Cybersecurity and SI/AI Strategy

NCUA must continue investing in modern information technology to keep pace with innovation while defending against evolving threats that could impact its ability to supervise America's credit unions. By integrating its cybersecurity framework with a forward-looking super intelligence/artificial intelligence (SI/AI) strategy, NCUA seeks to optimize business operations, harden agency systems against evolving digital threats, and foster a secure environment that supports responsible innovation across the credit union landscape.

The draft 2027–2028 budget includes resources to expand the agency's zero-trust cybersecurity strategy, with investments in advanced threat protection to address evolving digital risks and fulfill new federal requirements. To comply fully with federal directives, NCUA must acquire enhanced cybersecurity capabilities. The draft budget's investments will reduce reliance on manual processes, reinforce the organization's IT infrastructure, and ensure that NCUA can continue innovating by integrating SI/AI tools into its operations.

When combined with a portion of the agency's 2026 reorganization and innovation funding, the draft budget provides funding to continue deploying SI/AI and advanced analytic tools across the agency. NCUA's SI/AI strategy aligns with the Administration's direction and will both enhance examination and supervision capabilities and deliver operational efficiencies.

Deregulation, Examination Priorities, and Workforce

The draft 2027–2028 budget includes resources to reduce regulatory burden on credit unions and focus NCUA’s examination program on material risks.

NCUA’s Deregulation Project is a multi-year initiative to review, streamline, and modernize the agency’s regulatory framework. The Deregulation Project will continue in 2027, and will address more complex regulations with broader policy and operational implications. The draft budget supports this project and other rulemaking and related implementation efforts associated with new legislation and the Administration’s priorities, such as the Guiding and Establishing National Innovation for U.S. Stablecoins Act (GENIUS Act) for Permitted Payment Stablecoin Issuers.

NCUA continues to invest in its efforts to:

- Focus examination attention on areas posing material risk.
- Streamline examination practices to increase efficiency
- Adopt advanced capabilities to improve risk and problem identification
- Train, develop, and resource staff to ensure the agency has the necessary expertise to supervise complex and new activities
- Facilitate responsible innovation by credit unions

IV. Operating Budget: \$312.4 Million*Overview*

The proposed 2027 Operating Budget is \$312.4 million, which provides the resources required for the agency to conduct activities prescribed by the

FCU Act. These mandates include but are not limited to:

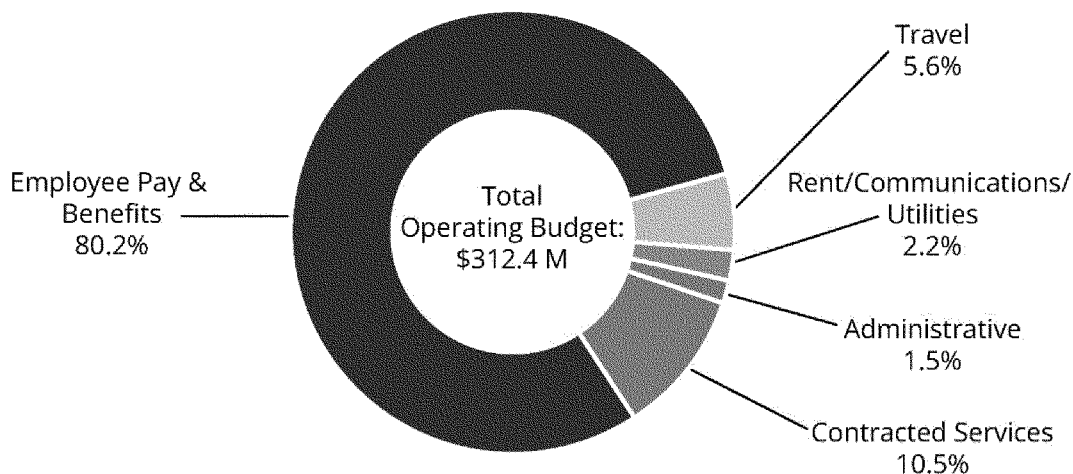
- Chartering new federal credit unions
- Approving field of membership applications of federal credit unions
- Promulgating regulations and providing guidance
- Performing examinations, supervision, and enforcement

NCUA also implements requirements of other statutes and Executive Orders including those related to the Bank Secrecy Act, various consumer financial protection laws, and various requirements for federal agencies.

Operating Budget Categories

This section explains how the Operating Budget funds NCUA’s major expense categories, as summarized in the following chart.

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2027 NCUA Operating Budget

Note: Minor rounding differences may occur in totals.

2027 – 2028 NCUA OPERATING BUDGET SUMMARY							
Budget Cost Category	2026 Board- Approved Budget	2027 Requested Budget	Change (2026-2027)	Percent Change (2026- 2027)	2028 Requested Budget	Change (2027-2028)	Percent Change (2027- 2028)
Employee Compensation	\$ 240,503,000	\$ 250,500,000	\$ 9,997,000	4.2%	\$ 260,339,000	\$ 9,839,000	3.9%
Salaries	\$ 164,456,000	\$ 171,314,000	\$ 6,858,000	4.2%	\$ 178,391,000	\$ 7,077,000	4.1%
Benefits	\$ 76,047,000	\$ 79,186,000	\$ 3,139,000	4.1%	\$ 81,948,000	\$ 2,762,000	3.5%
Travel	\$ 20,134,000	\$ 17,394,000	\$ -2,740,000	-13.6%	\$ 18,915,000	\$ 1,521,000	8.7%
Rent/Comms/Utilities	\$ 4,897,000	\$ 7,029,000	\$ 2,132,000	43.5%	\$ 7,241,000	\$ 212,000	3.0%
Administrative	\$ 3,809,000	\$ 4,611,000	\$ 802,000	21.1%	\$ 4,769,000	\$ 158,000	3.4%
Contracted Services	\$ 19,368,000	\$ 32,882,000	\$ 13,514,000	69.8%	\$ 39,736,000	\$ 6,854,000	20.8%
Total	\$ 288,711,000	\$ 312,416,000	\$ 23,705,000	8.2%	\$ 331,000,000	\$ 18,584,000	5.9%
Plus Carryover	\$ 49,297,000	\$ 39,293,000	\$ -10,004,000	-20.3%	\$ 35,543,000	\$ -3,750,000	-9.5%
Gross Budget	\$ 338,008,000	\$ 351,709,000	\$ 13,701,000	4.1%	\$ 366,543,000	\$ 14,834,000	4.2%

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Pay and Benefits. Pay and benefits make up approximately 80 percent of the proposed 2027 NCUA Operating Budget. The proposed 2027 budget for pay and benefits increases by 4.2 percent compared to 2026, for a total of \$250.5 million. There are three primary drivers of increased costs in 2027 for the pay and benefits category:

- Merit and locality pay increases for NCUA's employees, which are paid according to the terms of the agency's compensation agreement with its employee union and its merit-based pay system.¹⁰

- Contributions for employee health insurance, which are set by OPM and cannot be changed by NCUA.

- Costs associated with other mandatory employer contributions such as Social Security, Medicare, transportation subsidies, unemployment insurance, and workers' compensation, which are set by other agencies and cannot be changed by NCUA.

- The proposed 2028 budget for pay and benefits is estimated at \$260.3 million, a 3.9 percent increase from the proposed 2027 level.

The proposed 2027 and 2028 Operating Budgets support a total agency staffing level of 972 positions.¹¹ This is an increase of five positions (0.5 percent) compared to the agency's 2026 approved position level. NCUA's Strategic Hiring Committee will allocate these new positions to address emerging needs related to new legislation, such as

the GENIUS Act and the 21st Century Road to Housing Act, as well as for other emerging Administration and agency priorities, such as SI/AI implementation and cybersecurity enhancements.

Approximately 63 percent, or 609 proposed positions, would conduct NCUA's examination and supervision functions, while the remaining 37 percent, or 363 proposed positions, would perform other necessary functions, including legal services, policy development and analysis, and agency administration.

The following chart illustrates NCUA's approved position levels in recent years.

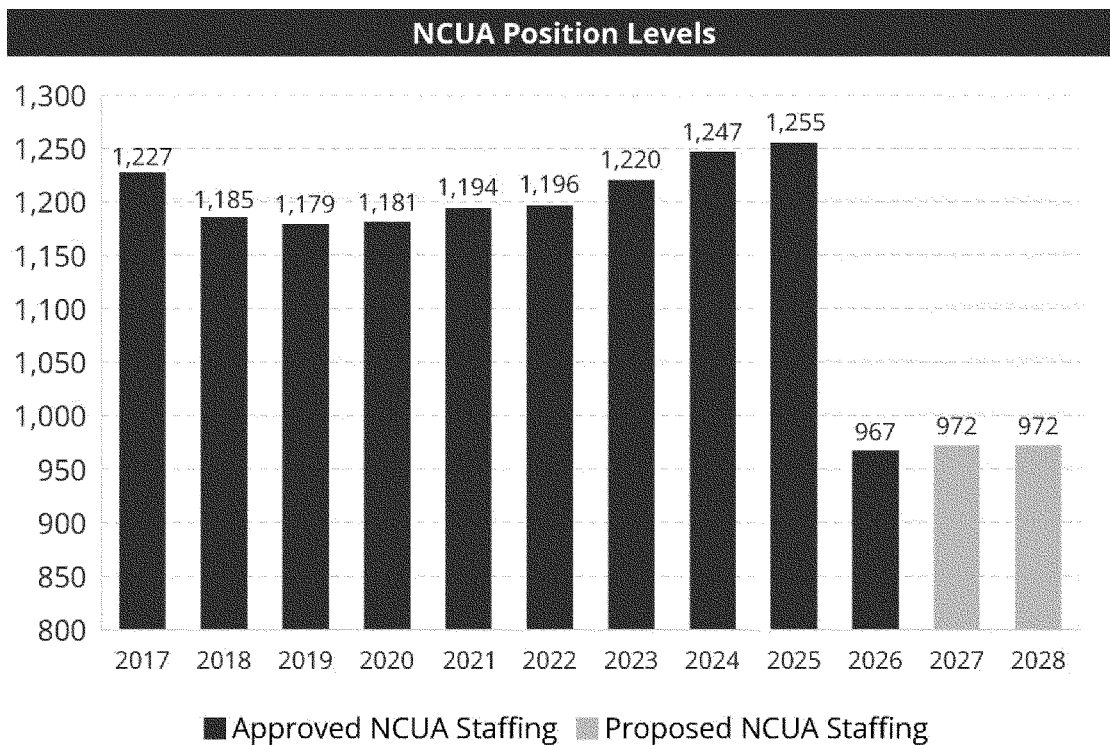
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¹⁰ The FCU Act requires NCUA to maintain pay comparability with the other banking agencies, stating, "In setting and adjusting the total amount of compensation and benefits for employees of the Board, the Board shall seek to maintain

comparability with other federal bank regulatory agencies." See 12 U.S.C. 1766(j)(2). Also, approximately 94 percent of NCUA's workforce has earned a bachelor's degree or higher, compared to

approximately 39 percent of the private-sector workforce.

¹¹ Does not include five positions assigned to the CLF.



Note: Position counts shown above exclude those funded by the Central Liquidity

Facility.

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Travel. The proposed travel budget decreases by \$2.7 million (13.6 percent) compared to 2026, for a total of \$17.4 million. The travel cost category includes expenses for employees' airfare, lodging, meals, auto rentals, reimbursements for privately owned vehicle usage, and other travel-related expenses. These are necessary expenses for onsite work in credit unions and other assignments involving travel.

The proposed 2028 budget for travel is estimated at \$18.9 million, an 8.7 percent increase compared to the 2027 level. This budget level reflects travel-related cost inflation in 2028 and an agency-wide training event.

Rent, Communications, and Utilities. The proposed budget for rent, communications, and utilities increases by \$2.1 million in 2027 (43.5 percent) compared to 2026, for a budget of \$7.0 million. The 2026 rent, communications, and utilities budget was reduced by a one-time offset of \$1.7 million from the sale of the Austin, TX office building.¹² Excluding this change

in the offset, the 2027 increase is \$0.4 million.

Funding within this budget category pays for facilities-related costs, telecommunications services, data storage, and information technology network support. Telecommunications charges include leased data lines and data service subscriptions, Voice over Internet Protocol and mobile telephony, and other network charges. Facilities-related budgets pay for the cost of the leased offices and disaster recovery and continuity of operations sites, utilities, meeting space rental for offsite events, and postage.

The proposed 2028 budget for the rent, communications, and utilities category is a 3.0 percent increase compared to 2027.

Administrative. The draft budget proposes a \$0.8 million increase in administrative expenses for 2027 (21.1 percent) compared to 2026, for a budget of \$4.6 million. Recurring costs in the administrative expenses category include employee relocation expenses, recruitment expenses, shipping, printing, subscriptions, examiner training and meeting supplies, office furniture, legal settlements, and employee supplies and materials. NCUA pays relocation costs to employees who

are competitively selected for a promotion or new job within the agency in a different geographic area than where they live.

The proposed 2028 budget for administrative expenses is \$4.8 million, an increase of 3.4 percent compared to the level proposed for 2027.

Contracted Services. The proposed budget for contracted services increases by \$13.5 million in 2027 (69.8 percent) compared to 2026, for a budget of \$32.9 million. The substantial percentage increase in the contracted services budget is driven largely by a reduction in the amount of prior-year unspent budget surpluses used to offset the 2027 budget.¹³ The proposed 2027 budget for contracted services assumes an offset of \$39.3 million from prior-year unspent budget balances. Excluding the offset, the 2027 proposed budget assumes total contracted services expenditures of \$72.2 million, compared to \$68.7 million in 2026, a 5.1 percent increase.

NCUA uses contracted services because acquiring specific expertise or services from contract providers is often the most viable and cost-effective way for NCUA to accomplish its mission.

¹² Some proceeds from the sale of the Austin, TX office building were also used to offset the Share Insurance Fund Administrative Expenses Budget because its purchase was partially funded by the Share Insurance Fund.

¹³ NCUA has historically applied unspent budget amounts from previous years to reduce its budget levels in the following two-year budget.

Contracted services include critical mission support such as information technology equipment and software development, accounting and auditing services, and specialized subject matter expertise that enable staff to focus on executing core mission requirements. The contracted services category supports NCUA's supervision framework, core NCUA systems such as accounting and payroll processing, and various recurring costs as described in the following seven major categories:

1. Information Technology Operations and Maintenance (50.7 Percent of Contracted Services)

- IT network support services and help desk support
- Contractor program and web support and network and equipment maintenance services
- Administration of software products and audio-visual services

2. Administrative Support and Other Services (16.4 Percent of Contracted Services)

- Examination and supervision program support
- Technical support for examination and cybersecurity training programs
- Equipment maintenance services
- Legal services and other expert consulting support
- FFIEC reimbursements

3. IT Security (16.9 Percent of Contracted Services)

- Secure data storage and operations
- Information security programs
- Security system assessment services

4. Accounting, Procurement, Payroll, and Human Resources Systems (4.6 Percent of Contracted Services)

- Accounting and procurement systems and support
- Human resources, payroll, and employee services
- Equal Employment Opportunity programs, as required by law

5. Building Operations, Maintenance, and Security (5.1 Percent of Contracted Services)

- Headquarters facility operations and maintenance
- Building security and continuity programs
- Personnel security and administrative programs

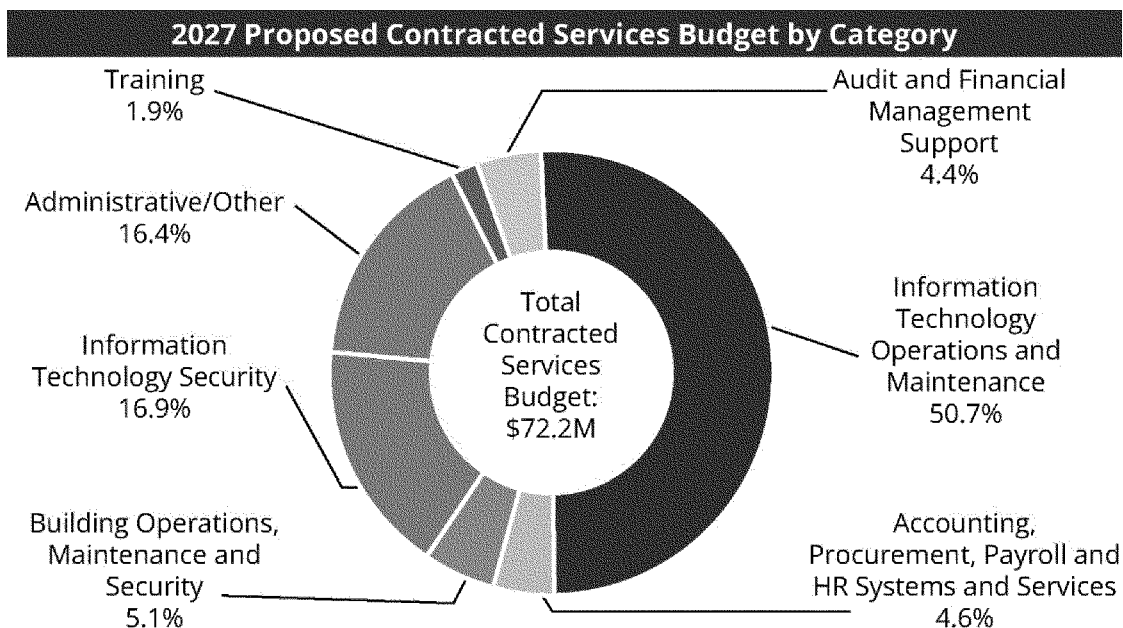
6. Audit and Financial Management Support (4.4 Percent of Contracted Services)

- Annual audit support services
- Material loss reviews
- Investigation support services
- Financial management support services

7. Training (1.9 Percent of Contracted Services)

- Technical and specialized training and professional development for staff

The following chart illustrates the breakout of the seven categories for the total proposed 2027 contracted services budget:



Note: Minor rounding differences may occur in totals.

The proposed contracted services budget for 2028 is \$39.7 million, which includes an assumption of \$35.5 million in unspent balances as an offset. After adjusting for unspent prior-year budgets in both years, the 2028 budget level

represents an increase of approximately \$3.1 million, or 4.3 percent, over the proposed 2027 level.

V. Capital Budget: \$7.9 Million

Overview

The proposed 2027 Capital Budget is \$7.9 million, a decrease of \$16.2 million (67.2 percent) compared to the 2026 Board-approved budget.

2027–2028 NCUA CAPITAL BUDGET							
	2026 Board- Approved Budget	2027 Requested Budget	Change (2026-2027)	Percent Change (2026-2027)	2028 Requested Budget	Change (2027-2028)	Percent Change (2027-2028)
Information Technology Investments	\$24,028,000	\$ 7,624,000	\$(16,404,000)	-68.3%	\$ 7,900,000	\$ 276,000	3.6%
Capital Building Improvements & Repairs	\$ 100,000	\$ 300,000	\$ 200,000	200.0%	\$ 100,000	\$ (200,000)	-66.7%
Total	\$24,128,000	\$ 7,924,000	\$(16,204,000)	-67.2%	\$ 8,000,000	\$ 76,000	1.0%

The proposed Capital Budget for 2028 is \$8.0 million, an increase of 1.0 percent compared to the 2027 level.

Summary of 2027 Capital Projects

Each year NCUA carries out an extensive review of the agency's needs for improvement, repair, or replacement of information technology, facilities, equipment, and other capital investments. The proposed 2027 Capital Budget supports continuing investments in the agency's highest priority needs as follows:¹⁴

Strengthening Agency Cybersecurity (\$4.7 million). The 2027 Capital Budget invests in multiple projects that directly strengthen cybersecurity at NCUA. These investments reinforce the agency's focus systems that are secure, available, and protected against emerging technological risks. Key projects within this category include:

- Firewall Hardware Refresh—Strengthens network perimeter defenses and reduces outage risks, which are core requirements for safe operations.

- Network Access Control / Network Segmentation—Supports identity-based cybersecurity, mitigating threats that target user identity.

- Modernizing Network Internet Protocols—Ensures NCUA can communicate with the public and credit unions using the latest digital communications standards.

- Identity Verification and Data Interchange Security—Modernizes and improves personal and system security through an enhanced technologies aligned to prevailing government and industry standards.

Modernizing Agency Systems and Workflow Transformation (\$1.7 million). The Capital Budget includes several investments to ensure the agency keeps pace with innovation across the credit union system. These projects adopt data-driven practices to expand access to financial services, support new credit unions, and strengthen the financial system. Key projects within this category include:

- Community Development Revolving Loan Fund (CDRLF) Grant &

Loan Management System—Modernizes the agency's outdated system to reduce staff workload and ensure compliance with federal grant management requirements.

- Consumer Assistance Center / Relationship Management System—Modernizes customer relationship management infrastructure and supports interagency collaboration.

- New Charter System Improvements—Fully digitizes chartering workflows, reduces burden for new credit union applicants, and meets requirements of the 21st Century Road to Housing Act.

- eDiscovery Tool—Strengthens legal research capabilities and reduces manual discovery through a modern data-filtering and investigation engine.

Enhancing Engagement, Transparency, and Operational Reliability (\$1.3 million). The Capital Budget strengthens technological readiness through investments that modernize communication with customers and enable compliance with evolving regulatory requirements. Key projects within this category include:

- Unified Communications and Collaboration Modernization—Improves hybrid meeting reliability for Board and public engagement functions.

- Technical Support for Board Priorities—Maintains flexibility to act on emerging regulatory changes that require system reengineering, such as the GENIUS Act and the 21st Century Road to Housing Act requirements.

Headquarters Building Minor Construction and Maintenance Projects (\$0.3 million). The proposed 2027 Capital Budget supports NCUA's multi-year headquarters building improvement plan that identifies projects that can be completed incrementally, prioritizing the replacement of health and safety infrastructure. The ongoing multi-year approach recognizes the critical building management and maintenance needs while reducing the potential budgetary impact of such projects in a single budget year.

Reorganization and Technology Investment Fund. The 2026 Capital

Budget included a \$16.0 million reorganization and technology investment fund—available over multiple years—to make appropriate information technology and process improvement investments that aid in the agency's reorganization. To ensure that NCUA can fully leverage SI/AI, the agency plans to allocate \$4.3 million of these funds to develop a structured strategy that harnesses SI/AI-powered tools essential for future supervision, analytics, and fraud detection. Through September 2026, the agency also spent approximately \$1 million on efficiency-related technology investments, business process analysis, and reorganization planning support.

VI. Share Insurance Fund Administrative Expenses Budget: \$5.1 Million

Overview

The proposed 2027 Share Insurance Fund Administrative Expenses Budget is \$5.1 million, which is \$1.7 million, or 52.6 percent, higher than the 2026 Board-approved budget. The 2026 Share Insurance Fund Administrative Expenses Budget was reduced by a one-time offset of \$1.7 million from the sale of the Austin, TX office building.¹⁵ Excluding this change in the offset, the proposed 2027 increase is \$0.04 million.

The Share Insurance Fund Administrative Expenses Budget funds direct costs associated with authorized Share Insurance Fund activities, including the following for 2027:¹⁶

- \$2.7 million for operating and maintenance costs of the internal analytical capabilities to conduct supervisory stress testing analyses and

¹⁵ Some of the proceeds for the sale were also used to offset the Share Insurance Fund Administrative Expenses Budget as it was partially funded by the Share Insurance Fund.

¹⁶ Direct costs do not include any costs that are shared with the Operating Fund through the OTR, and with payments available upon requisition by the Board, without fiscal year limitation, for insurance under Section 1787 of the FCU Act, and for providing assistance and making expenditures under Section 1788 of the FCU Act in connection with the liquidation or threatened liquidation of insured credit unions as it may determine to be proper.

¹⁴ See Appendix for more details.

to perform other quantitative risk assessments of large credit unions.

- \$0.8 million for state examiner travel to NCUA-sponsored training classes and \$0.2 million to ensure that state supervisory authorities can securely and efficiently access NCUA applications and NCUA's MERIT system for state examination and supervision activities.

- \$0.8 million for financial reporting, including the Share Insurance Fund's

annual financial audit and support to ensure effective internal controls for the fund.

- \$0.4 million for certain insurance-related activities and AMAC expenses related to liquidations and conservatorships and for staff travel for consultation on complex or problem cases.

- \$64.0 thousand for corporate resolution program legacy asset

valuation models, analytic support, and data.

- \$0.1 million in capital funding to modernize AMAC's liquidation support tracking tool. AMAC currently uses an end-of-life software platform to track various legal and financial claims during liquidation case management. In 2027, AMAC will deploy a modernized application to replace its current tool.

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2027 – 2028 SHARE INSURANCE FUND ADMINISTRATIVE EXPENSES BUDGET							
	2026 Board- Approved Budget	2027 Requested Budget	Change (2026- 2027)	Percent Change (2026- 2027)	2028 Requested Budget	Change (2027- 2028)	Percent Change (2027- 2028)
SIF Direct Expenses							
Travel							
OHR: State Examiner Training	1,120,000	807,000	(313,000)	-27.9%	831,210	24,210	3.0%
AMAC: Staff travel for problem cases	15,000	15,000	-	0.0%	15,450	450	3.0%
Subtotal, Travel (SIF Direct Expenses)	1,135,000	822,000	(313,000)	-27.6%	846,660	24,660	3.0%
Administrative Expenses							
ONES: Analytic Tools for Large Credit Unions	32,000	32,000	-	0.0%	32,960	960	3.0%
AMAC: Shipping and Miscellaneous Admin	48,000	48,000	-	0.0%	49,440	1,440	3.0%
Subtotal Administrative Expenses (SIF Direct Expenses)	80,000	80,000	-	0.0%	82,400	2,400	3.0%
Contracted Services							
ONES: Analytic Tools for Large Credit Unions	2,510,000	2,690,000	180,000	7.2%	2,770,700	80,700	3.0%
OCFO: Financial Accounting, Audit Support, Bank Charges and Other Support	785,000	756,000	(29,000)	-3.7%	778,680	22,680	3.0%
OBI: SSA costs for MERIT	216,000	216,000	-	0.0%	222,480	6,480	3.0%
AMAC: Legal support services, other contracts	220,000	320,000	100,000	45.5%	389,160	69,160	21.6%
Subtotal, Contracted Services (SIF Direct Expenses)	3,731,000	3,982,000	251,000	6.7%	4,161,020	179,020	4.5%
Capital Investments							
AMAC: Liquidation Support Tool Modernization	-	106,000	106,000	N/A	-	(106,000)	-100.0%
Total, SIF Direct Expenses	4,946,000	4,990,000	44,000	0.9%	5,090,080	100,080	2.0%
Corporate Resolution Program							
Administrative Expenses							
E&I: Software and Data Subscriptions	32,000	32,000	-	0.0%	32,960	960	3.0%
Contracted Services							
E&I: Valuation Services, Contract Support, Training	33,000	32,000	(1,000)	-3.0%	32,960	960	3.0%
Total, Corporate Resolution Program	65,000	64,000	(1,000)	-1.5%	65,920	1,920	3.0%
Subtotal, SIF Administrative Expenses	\$5,011,000	\$5,054,000	\$ 43,000	0.9%	\$5,156,000	\$ 102,000	2.0%
Proceeds from sale of Austin building	-1,700,000	-	1,700,000	-100.0%	-	-	0.0%
Total, SIF Administrative Expenses	\$3,311,000	\$5,054,000	\$1,743,000	52.6%	\$5,156,000	\$ 102,000	2.0%

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The proposed 2028 Share Insurance Fund Administrative Expenses budget is \$5.2 million, an increase of 2.0 percent compared to the proposed 2027 budget.

VII. Financing NCUA's Programs

Overview

NCUA incurs various expenses to satisfy its statutory requirements, including those involved in examining and supervising federally insured credit unions. The NCUA Board adopts an Operating Budget, a Capital Budget, and a Share Insurance Fund Administrative Expenses Budget each year to fund most of the costs to operate the agency.¹⁷ When formulating the annual budget, NCUA is mindful that its funding comes from credit unions and strives to operate in an efficient, effective, transparent, and fully accountable manner.

The FCU Act authorizes two primary sources to fund the Operating and Capital Budgets:

(1) Requisitions from the Share Insurance Fund “for such administrative and other expenses incurred in carrying out the purposes of [Title II of the Act] as [the Board] may determine to be proper,”¹⁸ and.

(2) “[F]ees and assessments (including income earned on insurance deposits) levied on insured credit unions under [the Act].”¹⁹ Among the fees levied under the Act are annual Operating Fees, which are required for federal credit unions under 12 U.S.C. 1755 “and may be expended by the Board to defray the expenses incurred in carrying out the provisions of [the Act], including the examination and supervision of [federal credit unions].”

Taken together, these authorities effectively require the Board to determine which expenses are appropriately paid from each source while giving the Board broad discretion in allocating expenses.

In 1973, the U.S. Government Accountability Office recommended NCUA adopt a method for allocating Operating Budget costs—that is, the portion of NCUA’s budget funded by

requisitions from the Share Insurance Fund and the portion covered by operating fees paid by federal credit unions.²⁰ NCUA has since used an allocation methodology known as the OTR to determine how much of the Operating and Capital Budgets to fund with a requisition from the Share Insurance Fund.

NCUA uses the OTR methodology to allocate agency expenses between these two primary funding sources. Specifically, the OTR is the formula NCUA uses to allocate insurance-related expenses to the Share Insurance Fund under Title II of the FCU Act. Almost all other operating expenses are funded by collecting annual operating fees from federal credit unions.²¹

Two statutory provisions directly limit the Board’s discretion with respect to Share Insurance Fund requisitions for NCUA’s Operating Budget and the OTR. First, expenses funded from the Share Insurance Fund must carry out the purposes of Title II of the FCU Act, which relates to share insurance.²² Second, NCUA may not fund its entire Operating Budget through charges to the Share Insurance Fund.²³

Overhead Transfer Rate

The OTR represents the percentage of the agency’s operating budget paid for by a transfer from the Share Insurance Fund. The OTR is designed to cover NCUA’s costs of examining and supervising the risk to the Share Insurance Fund posed by all federally insured credit unions, as well as the costs of administering the Share Insurance Fund.

Federally insured credit unions are not billed for and do not have to remit the OTR amount; instead, it is transferred directly to the Operating

Fund from the Share Insurance Fund. This transfer, therefore, represents an indirect cost to all federally insured credit unions.

The NCUA Board approved the current methodology for calculating the OTR at its November 2017 open meeting.²⁴ In 2023, the Board published a request for comment in the **Federal Register** regarding the OTR methodology but did not propose or adopt any changes to the current methodology.²⁵

The minor variations in the OTR since 2018 are the result of routine, small fluctuations in the variables that affect the OTR, including normal variations in the workload budget from one calendar year to the next.

NCUA conducts a comprehensive workload analysis annually. This analysis estimates the amount of time necessary to conduct examinations and supervise federally insured credit unions to carry out NCUA’s dual mission as insurer and regulator. This analysis starts with a field-level review of every federally insured credit union to estimate the number of workload hours needed for the year. These estimates are informed by the overall parameters of NCUA’s examination program, including workload estimates that are refined by regional managers and submitted to NCUA headquarters for the annual budget proposal. The OTR methodology excludes state regulator costs, including state examiner hours.

Based on the Board-approved methodology and the proposed budget, the OTR for 2027 is estimated to be 62.0 percent, which is an increase of 20 basis points from 2026. Thus, 62.0 percent of the proposed 2027 Operating Budget is estimated to be paid out of the Share Insurance Fund. The remaining 38.0 percent of the proposed 2027 Operating Budget is estimated to be paid for by operating fees collected from federal credit unions. The explicit and implicit distribution of total Operating Budget costs for federal credit unions and federally insured, state-chartered credit unions is shown in the table below:

²⁰ See www.gao.gov/products/b-1640314-31.

²¹ Annual operating fees must “be determined according to a schedule, or schedules, or other method determined by the NCUA Board to be appropriate, which gives due consideration to the expenses of the [NCUA] in carrying out its responsibilities under the [Act] and to the ability of [federal credit unions] to pay the fee.” 12 U.S.C. 1755(b).

²² 12 U.S.C. 1783(a).

²³ The Act in 12 U.S.C. 1755(a) states, “[i]n accordance with rules prescribed by the Board, each [federal credit union] shall pay to the [NCUA] an annual operating fee which may be composed of one or more charges identified as to the function or functions for which assessed.” See also 12 U.S.C. 1766(j)(3).

¹⁷ Some costs are directly charged to the Share Insurance Fund when appropriate to do so.

¹⁸ 12 U.S.C. 1783(a).

¹⁹ 12 U.S.C. 1766(j)(3). Other sources of income for the Operating Budget may include interest income, parking fee income, and rental income.

²⁴ 82 FR 55644 (Nov. 22, 2017).

²⁵ See www.federalregister.gov/documents/2023/12/20/2023-28000/request-for-comment-regarding-overhead-transfer-rate-methodology.

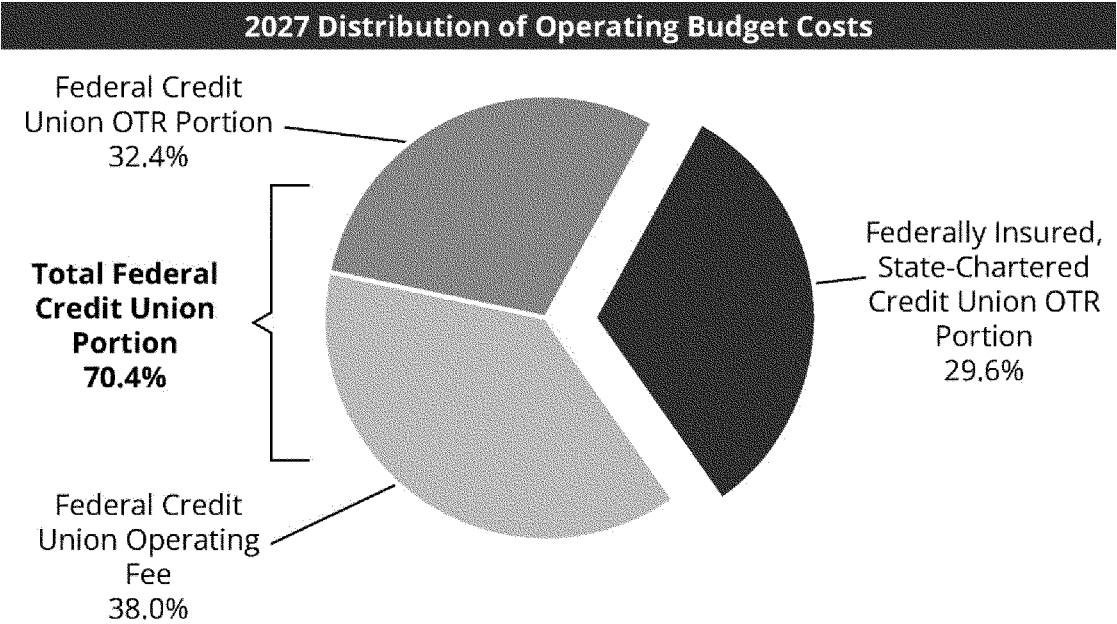
2027 Estimated Distribution: Overhead Transfer Rate and Operating Fee		
Est. Share of the Operating Budget covered by:	Federal Credit Unions	Federally Insured, State-Chartered Credit Unions
Federal Credit Union Operating Fee	38.0%	0.0%
Overhead Transfer Rate x Percent of Insured Shares	32.4% (62.0% x 52.2%)	29.6% (62.0% x 47.8%)
Total	70.4%	29.6%

Note: Percentages of insured shares shown above are as of June 30, 2026.

The following chart illustrates the share of the proposed 2027 Operating

Budget that would be paid by federal credit unions (70.4 percent) and

federally insured, state-chartered credit unions (29.6 percent).



Note: Federally insured, state-chartered credit unions typically pay supervisory fees to their respective State Supervisory Authority.

Operating Fee

The Board delegated authority to the Chief Financial Officer to calculate the annual operating fee for federal credit unions and to set the fee schedule as calculated using the approved methodology. In December 2023, the Board approved and published in the **Federal Register** the current operating fee methodology, which forms the basis for how the operating fee is calculated.²⁶

Under the current methodology to determine the annual operating fee assessed on natural person federal credit

unions, NCUA first calculates the average of total assets reported in the preceding four calendar quarters available at the time of the calculation, net of any reported Paycheck Protection Program loans.²⁷ Natural person federal credit unions with assets less than

²⁷ To determine the assessment scale for 2027, total growth in natural person federal credit union assets is calculated as the change between the average of the four most current quarters (that is, the third and fourth quarters of 2025 and the first two quarters of 2026) and the previous four quarters (that is, the third and fourth quarters of 2024 and the first two quarters of 2025). The result of the calculation is 4.81 percent. The fee exemption threshold and the asset level dividing points for the fee tiers are likewise increased by this same growth rate to preserve the same relative relationship of the scale to the applicable asset base.

approximately \$2.3 million are not assessed an operating fee and their assets are therefore excluded from this calculation.²⁸ Corporate federal credit unions also pay an annual operating fee based on a different scale.

Based on the Board-approved operating fee methodology, as shown in the following tables, the share of the proposed 2027 budget funded by the operating fee is \$116.9 million. The calculated operating fee rate for 2027 decreases by 49 basis points compared to the rate in 2026.

²⁸ The exemption threshold for 2027 is estimated at \$2,259,851 which accounts for 4.81 percent aggregate growth in credit union system assets.

²⁶ See www.federalregister.gov/documents/2023/12/26/2023-28303/national-credit-union-administration-operating-fee-schedule-methodology.

As part of the Board-approved operating fee methodology, NCUA analyzes the agency's future cash flow requirements compared to available balances. Any projected surplus cash from past years' fee collections that is not required to finance agency

operations can be used to lower the operating fee share of the proposed budget. Because these cash surpluses result from past years' operating fee collections, they do not offset the portion of the budget funded by the OTR. As the final 2027–2028 budget is

prepared for consideration by the NCUA Board, the Chief Financial Officer will evaluate the agency's cash position and make a recommendation about any surplus cash that can be credited to the operating fee.

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PROJECTED FISCAL YEAR 2027 OPERATING FEE REQUIREMENTS

(\$ in millions)

		2027 Draft Budget
1	Proposed Operating Budget	\$ 312.416
2	Add Capital Investments	\$ 7.924
3	Miscellaneous Revenue	\$ (0.620)
4	Operating Budget to apply OTR	\$ 319.720
5	Overhead Transfer Rate 62.0%	\$ (198.226)
6	Interest Income	\$ (4.642)
7	Net (sum lines 4 - 6)	\$ 116.852
8	Operating Fund adjustment	\$ -
9	Budgeted Operating Fee/Capital Requirements (sum lines 7 - 8)	\$ 116.852
10	Corporate Federal Credit Union Operating Fees	\$ (0.325)
11	Natural Person FCU Operating Fees Required (sum lines 9 -10)	\$ 116.527
12	Fees projected with Asset Growth of 4.81%	\$ (117.106)
13	Difference (lines 11 & 12)	\$ (0.579)
14	Average Rate Adjustment Indicated (line 13 divided by line 12)	-0.49%

Operating Fee Scale

To illustrate the rate for each asset tier for which operating fees are charged, the

table below shows the effect of the average 49 basis point decrease in the estimated 2027 annual operating fee for

natural person federal credit unions, using a \$2.3 million exemption threshold.

DRAFT – PROPOSED 2027 OPERATING FEE SCALE

2026 Natural Person Federal Credit Union Scale

Asset Level		Operating Fee Assessment
\$0	to \$2,156,137	\$0.00
\$2,156,137	to \$2,538,638,819	\$0.00 + 0.00014220 X total assets over \$0.00
\$2,538,638,819	to \$7,681,882,928	\$360,994 + 0.00004144 X total assets over \$2,538,638,819
\$7,681,882,928	and over	\$574,130 + 0.00001384 X total assets over \$7,681,882,928

2027 (Proposed) Natural Person Federal Credit Union Scale

Projected FCU asset growth rate	4.81%	Change in asset level dividing points
Operating fee rate change	-0.49%	Change in assessment rate percentages

Asset Level		Operating Fee Assessment
\$0	to \$2,259,851	\$0.00
\$2,259,851	to \$2,660,751,553	\$0.00 + 0.00014150 X total assets over \$0.00
\$2,660,751,553	to \$8,051,394,226	\$376,496 + 0.00004124 X total assets over \$2,660,751,553
\$8,051,394,226	and over	\$598,806 + 0.00001377 X total assets over \$8,051,394,226

2027 (Proposed) Corporate Federal Credit Union Scale

Asset Level		Operating Fee Assessment
\$50,000,000	to \$100,000,000	\$10,392 + 0.00019870 X total assets over \$50,000,000
\$100,000,000	and Over	\$20,327 + 0.00001230 X total assets over \$100,000,000

VIII. Appendix: Supplemental Budget Information

Office Budgets^{29 30}

2027-2028 NCUA OPERATING BUDGET							
Office	2026 Board- Approved Budget	2027 Requested Budget	Change (2026-2027)	Percent Change (2026- 2027)	2028 Requested Budget	Change (2027-2028)	Percent Change (2027- 2028)
Eastern Region	50,553,043	51,462,260	909,217	1.8%	53,197,437	1,735,177	3.4%
Southern Region	41,930,252	41,994,782	64,529	0.2%	43,397,876	1,403,094	3.3%
Western Region	48,087,121	49,495,197	1,408,075	2.9%	51,152,195	1,656,999	3.3%
Office of National Examinations and Supervision	11,521,134	11,377,123	(144,011)	-1.2%	11,762,906	385,783	3.4%
Office of Consumer Financial Protection	6,769,314	6,084,272	(685,042)	-10.1%	6,290,201	205,929	3.4%
Subtotal, Examination and Supervision	158,860,864	160,413,634	1,552,770	1.0%	165,800,616	5,386,982	3.4%
Office of the Board	4,123,808	4,199,565	75,757	1.8%	4,341,848	142,283	3.4%
Office of the Executive Director	1,019,665	1,695,926	676,261	66.3%	1,752,397	56,472	3.3%
Federal Financial Institutions Examination Council	2,052,000	2,102,000	50,000	2.4%	2,165,060	63,060	3.0%
Office of Ethics Counsel	1,720,166	2,097,945	377,780	22.0%	2,169,613	71,668	3.4%
Office of Business Innovation	3,201,376	2,599,164	(602,212)	-18.8%	2,687,146	87,982	3.4%
Office of Continuity and Security Management	5,357,675	5,942,532	584,857	10.9%	6,115,867	173,335	2.9%
Office of Minority and Women Inclusion	822,937	763,720	(59,217)	-7.2%	788,647	24,928	3.3%
Office of the Chief Financial Officer	23,952,893	24,674,681	721,789	3.0%	25,473,569	798,888	3.2%
Cross-cutting agency expenses	(44,038,328)	(34,226,845)	9,811,483	22.3%	(28,961,592)	5,265,253	15.4%
Office of the Chief Information Officer	62,483,094	66,944,427	4,461,333	7.1%	69,863,876	2,919,449	4.4%
Credit Union Resources and Expansion	8,549,789	9,053,215	503,426	5.9%	9,362,522	309,307	3.4%
Office of Examination & Insurance	19,603,459	20,229,176	625,717	3.2%	20,915,533	686,358	3.4%
Office of General Counsel	12,558,491	12,622,332	63,841	0.5%	13,054,036	431,704	3.4%
Office of Inspector General	4,123,600	4,799,298	675,698	16.4%	5,073,687	274,389	5.7%
Office of Human Resources	16,427,372	19,803,985	3,376,613	20.6%	21,404,806	1,600,822	8.1%
Office of External Affairs and Communication	1,369,810	1,681,760	311,951	22.8%	1,738,235	56,474	3.4%
Asset Management and Assistance Center	6,522,330	7,019,487	497,157	7.6%	7,254,134	234,648	3.3%
Subtotal, Other Offices	129,850,136	152,002,366	22,152,230	17.1%	165,199,385	13,197,019	8.7%
Total, Operating Budget	\$288,711,000	\$312,416,000	\$ 23,705,000	8.2%	\$ 331,000,000	\$ 18,584,000	5.9%

Note: Beginning in 2026 the Office of the Chief Economist has been incorporated into the Office of Examination and Insurance.

²⁹ Minor rounding differences may occur in totals.

³⁰ Budget allocations by office reflect NCUA's current organizational structure as the agency transitions to a new, streamlined organizational structure as part of its strategic restructuring plans. The reorganization process is actively underway and is expected to be completed by December 2027.

Capital Projects

NATIONAL CREDIT UNION ADMINISTRATION: CAPITAL INVESTMENT PROJECTS			
Description	2026 Board-Approved Budget	2027 Requested Budget	2028 Requested Budget
Strengthening Agency Cybersecurity			
Firewall Hardware Refresh	\$ -	\$ 3,000,000	\$ -
Network Access Control - Network Segmentation	\$ -	\$ 400,000	\$ -
Modernizing Network Internet Protocols (IPv6)	\$ -	\$ 350,000	\$ -
Certificate Management Solution	\$ -	\$ 300,000	\$ -
API Programming Services	\$ -	\$ 300,000	\$ -
Cloud-based SFTP File Sharing	\$ -	\$ 175,000	\$ -
PIV Certificate Mapping	\$ -	\$ 144,000	\$ -
On Premise Infrastructure Refresh	\$ 800,000	\$ -	\$ -
Network Connectivity and Resiliency	\$ 140,000	\$ -	\$ -
Modernizing Agency Systems and Workflow Transformation			
CDRLF Grant and Loan Management System	\$ -	\$ 605,000	\$ -
Consumer Assistance Center - Relationship Management System	\$ 1,000,000	\$ 500,000	\$ -
New Charter System Improvements	\$ -	\$ 300,000	\$ -
e-Discovery Tool	\$ -	\$ 300,000	\$ -
Enhancing Engagement, Transparency, and Operational Reliability			
Unified Communications and Collaboration (UCC) Modernization	\$ -	\$ 750,000	\$ -
Technical Support for Board Priorities	\$ -	\$ 500,000	\$ 500,000
Other Capital IT Projects			
Examination and Supervision Solution/MERIT Enhancements	\$ 2,898,000	\$ -	\$ -
Enterprise Laptop Refresh	\$ 3,190,000	\$ -	\$ -
Priority Investments for Reorganization and Operating Efficiencies	\$ 16,000,000	\$ -	\$ -
Anticipated Information Technology Investments	\$ -	\$ -	\$ 7,400,000
Total, Information Technology Investments	\$24,028,000	\$ 7,624,000	\$ 7,900,000
Capital Building Improvements and Repairs			
Central Office Maintenance and Repair	\$ 100,000	\$ 300,000	\$ 100,000
Grand Total, Capital Projects	\$24,128,000	\$ 7,924,000	\$ 8,000,000

Note: See Section V. Capital Budget for details on NCUA's use

of funds for Priority Investments for Reorganization and Operating

Efficiencies.

[FR Doc. 2026-21948 Filed 10-27-26; 8:45 am]
BILLING CODE 7535-01-C

NATIONAL SCIENCE FOUNDATION

**Agency Information Collection
Activities: Comment Request; National
Science Foundation Proposal/Award
Information—NSF Guidance on
Financial Assistance**

AGENCY: National Science Foundation.

ACTION: Submission for OMB review;
comment request.

SUMMARY: The U.S. National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register** and 3,277 responses were received, which NSF publicly posted 3,075; any comments not publicly posted were either out of scope or

duplicates. NSF is forwarding the proposed renewal submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

DATES: 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:

Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, Randolph Building, 401 Delany Street, Alexandria, Virginia 22314; telephone (703) 292-7556; or send email to fafrquestions@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).

NSF 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.

SUPPLEMENTARY INFORMATION:

Abstract: NSF made the draft NSF GFA available for review by the public between June 24 and August 23, 2026. NSF received 3,277 responses in response to the **Federal Register** notice at 91 FR 38030. NSF publicly posted 3,075 comments that it determined were relevant to the draft GFA. Any comments not publicly posted were either out of scope with the content of the notice or duplicates. All in-scope comments have been considered in the development of the proposed version. A summary of the significant changes and clarifications to the GFA has been incorporated into the document.

The primary purpose of this revision is to update NSF policies through the development of the U.S. NSF *Proposal and Award Policies and Procedures Guide* (PAPPG), now to be renamed the NSF *Guidance on Financial Assistance* (GFA), to incorporate plain language, clarify language, separate policies from procedures, remove policies no longer relevant, incorporate mandated statutory, regulatory, executive order, and policy-related changes. The GFA directs users to originating statutes, guidance, and regulations, where practicable.

Title of Collection: “U.S. National Science Foundation Proposal/Award Information—NSF Guidance on Financial Assistance”

OMB Approval Number: 3145-0058.

Type of Request: NSF intends to seek approval to extend with revision an information collection for three years.

Background: The U.S. National Science Foundation (NSF) was

established by the National Science Foundation Act of 1950 (Pub. L. 81-507), as amended, to “promote the progress of science; to advance the national health, prosperity, and welfare; to secure the national defense.” The Act authorizes NSF to initiate and support fundamental research, strengthen scientific and engineering research capabilities, advance science and engineering education, and undertake other activities consistent with its statutory mission.

Use of the Information: The regular submission of proposals to NSF is part of the collection of information and is used to help the agency fulfill this responsibility by initiating and supporting merit-selected research and education projects in all the scientific and engineering disciplines. NSF receives more than 43,000 proposals annually for new projects and makes approximately 8,300 financial assistance awards, including grants and cooperative agreements. NSF funding is primarily made through issuance of grants and cooperative agreements awarded to approximately 3,000 institutions of higher education, non-profit organizations, tribal nations, for-profit organizations, and state and local governments. The awards are based primarily on the merit review of proposals submitted to the Foundation.

Burden on the Public: NSF estimates that a range of between 120 to 360 hours are expended for each proposal submitted depending on proposal complexity. An estimated 43,000 proposals are expected to be received during the course of one year for around 5.16 to 15.48 million public burden hours annually.

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; and (e) feedback on the new design and display of information for users. Comments, including attachments to [regulations.gov](https://www.regulations.gov), will be posted publicly

to the docket unchanged. Commenters are encouraged to provide clarity as to the guide number and section that each comment is referencing by beginning each comment with the relevant section number in brackets. For example; if the comment is on Guide 2, Section A. Term and Definition 2. Dear Colleague Letters (DCLs), include the following before the comment [G2.A.Term 2].

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2026-21979 Filed 10-27-26; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70-7033; CEQ ID EISX-429-00-000-1754990851; NRC-2025-1007]

Global Laser Enrichment, LLC; Paducah Laser Enrichment Facility; Final Environmental Impact Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued a final environmental impact statement (EIS) regarding a license application from Global Laser Enrichment, LLC (GLE) to construct and operate the Paducah Laser Enrichment Facility. The EIS evaluates the environmental impacts of the proposed action of issuing a license that would authorize GLE to construct and operate a uranium enrichment facility on a 322-acre site located in McCracken County, Kentucky, approximately 5 miles west of Paducah.

DATES: The final EIS was made publicly available on October 23, 2026.

ADDRESSES: Please refer to Docket ID NRC-2025-1007 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-1007. Address questions about Docket IDs in [Regulations.gov](https://www.regulations.gov) to Bridget Curran; telephone: 301-415-1003; email: Bridget.Curran@nrc.gov. For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at

<https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin ADAMS Public Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The final EIS is available in ADAMS under Accession No. ML26286A042.

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

- **Public Library:** A copy of the final EIS for GLE’s license application for the Paducah Laser Enrichment Facility will be available for public review at the McCracken County Public Library, 555 Washington St., Paducah, KY 42003.

FOR FURTHER INFORMATION CONTACT: Amy Hester Minor, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 817–200–1454; email: Amy.Hestermminor@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 51.118 of title 10 of the *Code of Federal Regulations* (10 CFR), “Final environmental impact statement—notice of availability,” the NRC is providing notice that the final EIS regarding GLE’s license application for the Paducah Laser Enrichment Facility is available for public inspection. The NRC issued a draft EIS regarding this license application on March 23, 2026 (ADAMS Accession No. ML26061A085) and published a **Federal Register** (FR) notice on March 27, 2026 (91 FR 14882) to request comments on the draft EIS. The public comment period for the draft EIS ended on May 11, 2026. The final EIS includes responses to comments on the draft EIS and conforming changes where appropriate.

II. Discussion

The NRC has prepared a final EIS regarding GLE’s application for a license to construct and operate a uranium enrichment facility on a 322-acre greenfield site in McCracken County, Kentucky. The proposed Federal action is the issuance of a license that would authorize GLE to receive title to, own, acquire, receive, possess, use, transfer, and/or deliver source material, special

nuclear material, and byproduct material as specified in the license for the purposes of constructing, and then operating for up to 40 years, a facility that uses laser-based isotope separation technology to enrich uranium. The facility would be authorized to re-enrich depleted uranium hexafluoride (DUF₆) tails to natural levels and enrich natural-grade UF₆ up to 8 percent uranium-235 (U–235) by weight.

The final EIS contains the NRC staff’s analysis that evaluates the environmental impacts of the proposed action and the no-action alternative to the proposed action. The final EIS also contains the NRC staff’s final recommendation on the action to be taken, which is based on the following factors:

- The NRC staff’s review of GLE’s environmental report, other information in GLE’s license application, and associated responses from GLE to requests from the NRC staff for clarifying information;
- The NRC staff’s consideration of comments received as part of the scoping process;
- The NRC staff’s communications with Federal, State, and local agencies, as well as Tribal officials;
- The NRC staff’s consideration of comments on the draft EIS; and
- The NRC staff’s independent environmental review.

The NRC staff’s final recommendation, unless safety issues mandate otherwise, is that the NRC issue the license to construct and operate the proposed enrichment facility to GLE.

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

Dated: October 26, 2026.

For the Nuclear Regulatory Commission.

Kimyata Savoy,

Director, Division of Storage of Fuel, Transportation, and Environmental, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2026–21996 Filed 10–27–26; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2027–18 and K2027–19; MC2027–19 and K2027–20]

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:

Table of Contents

- I. Introduction
- II. Public Proceeding(s)
- III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service’s request(s) can be accessed via the Commission’s website (<http://www.prc.gov>). Non-public portions of the Postal Service’s request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request’s acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service’s request(s) identified in Section II, if any, are consistent with the policies of title 39.

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).

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.

III. Summary Proceeding(s)

1. *Docket No(s):* MC2027–18 and K2027–19; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1116, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 23, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

2. *Docket No(s):* MC2027–19 and K2027–20; *Filing Title:* USPS Request to Add New Mid-Market Standardized Distinct Product, PM–GA Contract 1117, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 23, 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. 2026–21971 Filed 10–27–26; 8:45 am]
BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage Negotiated Service Agreements; Priority Mail and USPS Ground Advantage Negotiated Service Agreements

AGENCY: Postal Service.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* October 28, 2026.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), it filed with the Postal Regulatory Commission the following requests:

Date filed with postal regulatory commission	Negotiated service agreement product category and No.	MC docket No.	K docket No.
10/15/26	PM-GA 1111	MC2027–10	K2027–11
10/15/26	PM-GA 1112	MC2027–11	K2027–12
10/15/26	PM-GA 1113	MC2027–12	K2027–13
10/16/26	PME-PM-GA 1513	MC2027–13	K2027–14
10/19/26	PME-PM-GA 1514	MC2027–14	K2027–15
10/19/26	PM-GA 1114	MC2027–15	K2027–16
10/21/26	PM-GA 1115	MC2027–16	K2027–17
10/23/26	PM-GA 1116	MC2027–18	K2027–19
10/23/26	PM-GA 1117	MC2027–19	K2027–20

Documents are available at www.prc.gov.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2026–21915 Filed 10–27–26; 8:45 am]
BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36370; 812–16011]

Valued Advisers Trust and Long Short Advisors, LLC

October 26, 2026.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (“Act”) for an exemption from section 15(a) of the Act, as well as from certain disclosure requirements in rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934, and sections 6–07(2)(a), (b), and (c) of Regulation S–X (“Disclosure Requirements”).

SUMMARY OF APPLICATION: The requested exemption would permit Applicants to enter into and materially amend subadvisory agreements with subadvisers without shareholder approval and would grant relief from the Disclosure Requirements as they relate to fees paid to the subadvisers.

APPLICANTS: Valued Advisers Trust and Long Short Advisors, LLC.

FILING DATES: The application was filed on March 30, 2026, and amended on June 26, 2026, and September 25, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at Secretarys-Office@sec.gov and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time on November 20, 2026, and should be accompanied by proof of service on the Applicants, in

the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission’s Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*. Applicants: Kate A. McCurry, *KMcCurry@ktslaw.com*, Kilpatrick Townsend & Stockton LLP, 1001 West Fourth Street, Winston-Salem, NC 27101.

FOR FURTHER INFORMATION CONTACT: Erin Loomis Moore, Senior Counsel, or Matthew Cook, Branch Chief, at (202) 551–6720 or *IMOCC@sec.gov* (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: For Applicants’ representations, legal analysis, and conditions, please refer to Applicants’ second amended application, dated September 25, 2026, which may be obtained via the Commission’s website by searching for the file number at the top of this document, or for an Applicant using the Company name search field on the SEC’s EDGAR system. The SEC’s EDGAR system may be searched at <https://www.sec.gov/search-filings>. You may also call the SEC’s Office of Investor Education and Assistance at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026–22011 Filed 10–27–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36369; File No. 813–00404]

The Carlyle Group Inc. and CP VIII Coinvestment B, L.P.

October 23, 2026.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).

ACTION: Notice.

Notice of application for an order (“Order”) under sections 6(b) and 6(e) of the Investment Company Act of 1940 (the “Act”) granting an exemption from all provisions of the Act, except sections 9, 17, 30, and 36 through 53, and the rules and regulations under the Act (the

“Rules and Regulations”). With respect to sections 17(a), (d), (e), (f), (g), and (j) of the Act, sections 30(a), (b), (e), and (h) of the Act and the Rules and Regulations and rule 38a–1 under the Act, Applicant requests a limited exemption as set forth in the application.

SUMMARY OF APPLICATION: Applicants request an order to exempt certain limited partnerships, limited liability companies, corporations, business or statutory trusts or other entities (“Partnerships”) formed for the benefit of eligible employees of Applicants and their affiliates from certain provisions of the Act. Each Partnership, and each Series thereof, will be an “employees’ securities company” within the meaning of section 2(a)(13) of the Act.

APPLICANTS: The Carlyle Group Inc. and CP VIII Coinvestment B, L.P.

FILING DATES: The application was filed on December 28, 2021, and amended on May 20, 2022, December 1, 2022, July 29, 2025, and October 22, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at *Secretarys-Office@sec.gov* and serving Applicant with a copy of the request by email, if an email address is listed for Applicant below, or personally or by mail, if a physical address is listed for Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on November 17, 2026, and should be accompanied by proof of service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission’s Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*. Applicant: Jeffrey W. Furgeson, The Carlyle Group Inc., Kate Heinzelman; and Rajib Chanda, *Rajib.Chanda@stblaw.com*, and Neesa Sood, *Neesa.Sood@stblaw.com*, Simpson Thacher & Bartlett LLP.

FOR FURTHER INFORMATION CONTACT: Stephan N. Packs, Senior Counsel, or Matthew Cook, Branch Chief, at (202) 551–6720 or *IMOCC@sec.gov* (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: For Applicant’s representations, legal analysis, and conditions, please refer to Applicant’s fourth amended application, dated October 22, 2026, which may be obtained via the Commission’s website by searching for the file number at the top of this document, or for Applicant using the Company name search field, on the SEC’s EDGAR system. The SEC’s EDGAR system may be searched at <https://www.sec.gov/search-filings>. You may also call the SEC’s Office of Investor Education and Assistance at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2026–21933 Filed 10–27–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0237]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Form N–54A

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (the “Investment Company Act”), certain investment companies can elect to be regulated as business development companies, as defined in Section 2(a)(48) of the Investment Company Act (15 U.S.C. 80a–2(a)(48)). Under Section 54(a) of the Investment Company Act (15 U.S.C. 80a–53(a)), any company defined in Section 2(a)(48)(A) and (B) may elect to be subject to the provisions of Sections 55 through 65 of the Investment Company Act (15 U.S.C. 80a–54 to 80a–64) by filing with the Commission a notification of election, if such company has: (1) a class of equity securities registered under Section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (“Exchange Act”); or

(2) filed a registration statement pursuant to Section 12 of the Exchange Act for a class of its equity securities. The Commission adopted Form N-54A (17 CFR 274.53) as the form for notification of election to be regulated as a business development company.

The purpose of Form N-54A is to notify the Commission that the investment company making the notification elects to be subject to Sections 55 through 65 of the Investment Company Act, enabling the Commission to administer those provisions of the Investment Company Act to such companies.

The Commission staff estimates that on average approximately 25 business development companies file these notifications each year.¹ Each of those business development companies need only make a single filing of Form N-54A. The Commission staff further estimates that such business development companies will each spend 0.5 hours at a cost of \$470.5 per hour preparing the form, resulting in a total annual time burden of 12.5 hours. Based on the estimated wage rate, the total cost to the business development company industry of the hour burden for complying with Form N-54A would be approximately \$5,881.25.

The Commission staff estimates that there is no additional cost burden associated with the form other than the cost of the burdens identified above.

The collection of information under Form N-54A is mandatory. The information provided by the form is not kept confidential.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202608-3235-012 or email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice, by November 30, 2026.

Dated: October 26, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-22002 Filed 10-27-26; 8:45 am]

BILLING CODE 8011-01-P

¹ This number is based on the average annual number of Form N-54A filings with the Commission from January 1, 2023 through December 31, 2025.

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235-0222]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Rule 17f-1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 17f-1 (17 CFR 270.17f-1) under the Investment Company Act of 1940 (the "Act") (15 U.S.C. 80a) is entitled: "Custody of securities with members of national securities exchanges." Rule 17f-1 provides that any registered management investment company ("fund") that wishes to place its assets in the custody of a national securities exchange member may do so only under a written contract that must be ratified initially and approved annually by a majority of the fund's board of directors. The written contract also must contain certain specified provisions. In addition, the rule requires an independent public accountant to examine the fund's assets in the custody of the exchange member at least three times during the fund's fiscal year. The rule requires the written contract and the certificate of each examination to be transmitted to the Commission. The purpose of the rule is to ensure the safekeeping of fund assets.

Commission staff estimate that each fund makes 1 response and spends an average of 3.5 hours annually in complying with the rule's requirements. Commission staff estimate that on an annual basis it takes: (i) 0.5 hours for the board of directors¹ to review and ratify the custodial contracts; and (ii) 3 hours for the fund's controller to assist the fund's independent public auditors in verifying the fund's assets. Approximately 4 funds rely on the rule

¹ Estimates of the number of hours are based on conversations with representatives of mutual funds that comply with the rule. The actual number of hours may vary significantly depending on individual fund assets. The hour burden for rule 17f-1 does not include preparing the custody contract because that would be part of customary and usual business practice.

annually, with a total of 4 responses.² Thus, the total annual internal hour burden for rule 17f-1 is approximately 14 hours.³

Funds that rely on rule 17f-1 generally use a lawyer to prepare the custodial contract for the board's review and to transmit the contract to the Commission. Commission staff estimate the cost of a lawyer to perform these tasks for a fund each year is \$1,548.⁴ Funds also must have an independent public accountant verify the fund's assets three times each year and prepare the certificate of examination. Commission staff estimates the annual cost for an independent public accountant to perform this service is \$11,550.⁵ Therefore, the total annual cost burden for a fund that relies on rule 17f-1 would be approximately \$13,098.⁶ As noted above, the staff estimates that 4 funds rely on rule 17f-1 each year, for an estimated total annualized external cost burden of \$52,392.⁷

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Compliance with the collections of information required by rule 17f-1 is mandatory for funds that place their assets in the custody of a national securities exchange member. Responses will not be kept confidential.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information

² This estimate is based on a review of Form N-17f-1 filings over the last three years. In 2023 there were six unique filers, in 2024 there were three unique filers, and in 2025 there were four unique filers. $(6 + 3 + 4)/3 = 4.33$ funds, rounded down to an estimated 4 funds. $4 \text{ funds} \times 1 \text{ response per filer} = 4 \text{ responses}$.

³ This estimate is based on the following calculation: $(4 \text{ respondents} \times 3.5 \text{ hours} = 14 \text{ hours})$. The annual burden for rule 17f-1 does not include time spent preparing Form N-17f-1. The burden for Form N-17f-1 is included in a separate collection of information.

⁴ This estimate is based on the following calculation: $(2 \text{ hours of outside counsel time} \times \$774 = \$1,548)$. To calculate the occupational hourly rates used in this release, the Commission uses occupational mean hourly wage data from the Occupational Employment and Wage Statistics ("OEWS") program of the Bureau of Labor Statistics ("BLS") for "Securities, Commodity Contracts, and Other Financial Investments and Related Activities" ("NAICS 523").

⁵ Commission staff estimates that this would require approximately 35 hours for an accountant to complete at a cost of approximately \$330 per hour. $35 \text{ hours} \times \$330 = \$11,550$. The occupational wage rate was derived using wage data from the OEWS program of BLS for NAICS 523.

⁶ This estimate is based on the following calculation: $\$1,548 + \$11,550 = \$13,098$.

⁷ This estimate is based on the following calculation: $4 \text{ funds} \times \$13,098 = \$52,392$.

unless it displays a currently valid control number.

The public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202608-3235-011 or email comment to MBX.OMB.OIRA.SEC_desklowbar;officercommat;omb.eop.gov within 30 days of the day after publication of this notice, by November 30, 2026.

Dated: October 26, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22001 Filed 10–27–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106726; File No. 4–930]

Order Under Section 36 of the Securities Exchange Act of 1934 Granting Conditional Exemptive Relief Regarding the Treatment of Customer Margin Under Item 13 and Note F of Exhibit A to Rule 15c3–3

October 23, 2026.

I. Introduction

A. Overview of the Exemptive Order

On September 18, 2026, Cboe Clear U.S., LLC (“CCUS”), a clearing agency now temporarily registered with the Securities and Exchange Commission (“Commission”) pursuant to Rule 17Ab2–1(c)¹ under the Securities Exchange Act of 1934² (“Exchange Act”) for a period of 18 months,³ filed an application with the Commission (“Application”)⁴ to obtain an exemption pursuant to section 36(a)(1)⁵ of the Exchange Act, in accordance with the procedures set forth in Exchange Act

Rule 0–12.⁶ Specifically, CCUS requested exemptive relief on behalf of broker-dealers that are CCUS clearing members (“Clearing Members”) from the limitation in Item 13 and Note F of Exhibit A to Rule 15c3–3⁷ that confines the Item 13 debit to the amount of margin required and on deposit with the Options Clearing Corporation (“OCC”) for all option contracts written or purchased in customer accounts. This would afford Clearing Members the same treatment for margin required and on deposit at CCUS for purposes of the reserve computation requirements under Item 13 and Note F of Rule 15c3–3a as is currently afforded to margin required and on deposit with the OCC.⁸

On September 25, 2026, the Commission published a notice of an application for an exemption and requested comment regarding the Application and the proposed conditions set forth therein.⁹ The Notice was published in the **Federal Register** on September 29, 2026.¹⁰ The Commission received one comment on the Notice of an Application.¹¹ For the reasons discussed below, this order grants Clearing Members conditional exemptive relief from the limitation in Item 13 and Note F of 15c3–3a that confines the Item 13 debit to margin required and on deposit with the OCC for all option contracts written or purchased in customer accounts.

B. Overview of Rule 15c3–3 and Rule 15c3–3a

Rule 15c3–3, the broker-dealer customer protection rule, requires, among other things, broker-dealers that hold customer cash and securities (“carrying broker-dealers”) to compute the net amount of cash owed to customers under a formula in Rule 15c3–3a (“customer reserve computation”).¹² Generally, carrying broker-dealers must perform this customer reserve computation and make

any required deposit into special reserve bank account daily or weekly. The rule also requires a carrying broker-dealer to perform a PAB reserve computation for the proprietary securities and cash it holds for other broker-dealers, known as proprietary accounts of broker-dealers (“PAB accounts”).¹³ Item 13 of the customer reserve computation in Rule 15c3–3a includes as a debit in the computation the amount of margin required and on deposit with OCC for all option contracts written or purchased in customer accounts. Note F to Item 13 states that Item 13 must include the amount of margin required and on deposit with the OCC to the extent such margin is represented by cash, proprietary qualified securities and letters of credit collateralized by customers’ securities.¹⁴ Under that framework, the permitted debit is based on the margin amount posted by the broker-dealer to OCC that is calculated by OCC across all of the broker-dealer’s customers with listed options (*i.e.*, on an omnibus basis).

C. Request for Exemptive Relief From CCUS

In its Application, CCUS requested, pursuant to section 36(a)(1) of the Exchange Act, and in accordance with the procedures set forth in Rule 0–12, that the Commission issue an order exempting its Clearing Members from the limitation in Item 13 and Note F of Rule 15c3–3a that confines the Item 13 debit to the amount of margin required and on deposit with OCC for option contracts written or purchased in customer accounts. CCUS also requested that the exemptive relief apply with respect to the PAB reserve computation.¹⁵ In effect, CCUS is seeking comparable treatment for its Clearing Members under the customer reserve computation with respect to the margin that is required and on deposit at CCUS as has been afforded broker-dealers that are clearing members of OCC.

In support of its request, CCUS stated that when the Commission adopted Item 13, and Note F thereto, OCC was the only clearing agency registered with the Commission to provide central counterparty services for securities options. CCUS stated that it does not

¹ 17 CFR 240.17Ab2–1(c).

² 15 U.S.C. 78a *et seq.*

³ See Exchange Act Rel. No. 34–106723 (October 22, 2026) (“CCUS Temporary Registration Order”) (granting CCUS’s request for temporary registration with an exemption from certain requirements for a period of 18 months). Pursuant to the CCUS Temporary Registration Order, CCUS is registered to provide central counterparty services for cash-settled binary security options, including security options overlying key performance indicators reported by certain issuers of stock. *Id.*

⁴ Letter from Dale Michaels, Head of Clearing, CCUS, to Vanessa A. Countryman, Secretary, Commission (Sept. 18, 2026); See also *infra* note 9.

⁵ 15 U.S.C. 78mm. Section 36(a)(1) of the Exchange Act gives the Commission the authority to exempt any person, security or transaction or any class or classes of persons, securities or transactions, conditionally or unconditionally, from any Exchange Act provision by rule, regulation or order, to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors.

⁶ 17 CFR 240.0–12. Exchange Act Rule 0–12 sets forth the procedures for filing applications for orders for exemptive relief pursuant to section 36.

⁷ 17 CFR 240.15c3–3a (“Rule 15c3–3a”).

⁸ See Application, at 1.

⁹ See Notice of an Application of Cboe Clear U.S., LLC for an Exemption Pursuant to Section 36 of the Securities Exchange Act of 1934 Regarding the Treatment of Customer Margin Under Item 13 and Note F of Exhibit A to Rule 15c3–3, Exchange Act Release No. 106493 (Sep. 25, 2026), 91 FR 61528 (Sep. 29, 2026) (“Notice of an Application”). The Application is attached as an appendix to the Notice of an Application and is available at: <https://www.sec.gov/files/rules/other/2026/34-106493.pdf>.

¹⁰ *Id.*

¹¹ See Letter from Shawn SN, dated October 13, 2026. The public comment file is available at <https://www.sec.gov/rules-regulations/public-comments/4-930>.

¹² 17 CFR 240.15c3–3.

¹³ Broker-dealers use the formula in Rule 15c3–3a for the purposes of computing the PAB reserve requirement, except that references to “accounts,” “customer accounts,” or “customers” will be treated as references to PAB accounts. See Note 1 to Rule 15c3–3a. For the purposes of this order, references to “accounts,” “customer,” or “customer accounts” will also include “PAB” or “PAB accounts.”

¹⁴ See Note F to Rule 15c3–3a.

¹⁵ See Application, at 3–4.

believe that the Exchange Act requires or warrants different treatment for margin held on similar terms for security option products at different registered clearing agencies. Further, CCUS stated that section 17A(a)(2) of the Exchange Act¹⁶ directs the Commission, with due regard for the maintenance of fair competition among clearing agencies, to facilitate a national system for the prompt and accurate clearance and settlement of securities transactions and to assure equal regulation under the Exchange Act of registered clearing agencies. Consequently, CCUS stated that reading Item 13 to exclude margin held at a second registered options clearing agency because it did not exist when the rule was amended would be inconsistent with this statutory mandate.¹⁷

To further support its position, CCUS stated that Item 14¹⁸ and Item 15¹⁹ of the customer reserve computation do not name any particular clearing agency, and do not distinguish between registered clearing agencies.²⁰ CCUS stated that where the Commission anticipated that more than one clearing agency could hold margin, it framed the customer reserve computation treatment of such margin by reference to a registered category rather than name a specific existing clearing agency.²¹ Consequently, CCUS stated that permitting broker-dealers to treat margin held at other registered clearing agencies would treat functionally equivalent margin on equivalent terms.²²

Additionally, CCUS stated that its proposed rules contemplate customer protection standards that satisfy the same regulatory requirements as those

under which OCC operates. Specifically, CCUS stated that it will offer separate customer, firm, and market-maker accounts, and that its rules require all funds and assets held for securities customers of a Clearing Member be maintained in a segregated Securities Customer Account. Further, CCUS stated that the binary options it proposed to clear will be fully margined and that its risk management framework provides for daily and intraday margin collection, guaranty fund resources, and a default waterfall.²³

In its Application, CCUS stated that a failure to provide equivalent treatment under the customer reserve computation to margin required and on deposit at CCUS would result in its Clearing Members facing a customer reserve computation penalty for clearing customer security options at CCUS. CCUS stated that this result could hinder the development of a cleared securities environment for trading in binary options that CCUS expects to clear.²⁴

In connection with its request for an exemption, CCUS proposed certain conditions that would apply in connection with its Clearing Members being able to include margin required and on deposit with CCUS with respect to customer binary options transactions in the Item 13 debit.²⁵

IV. Discussion

A. Statement of Relief

Section 36(a)(1) of the Exchange Act authorizes the Commission to conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from certain provisions of the Exchange Act or certain rules or regulations thereunder, by rule, regulation, or order, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.²⁶ As described below, the Commission finds that the conditional exemptive relief granted herein to permit Clearing Members to include an Item 13 debit for margin required and on deposit with CCUS in the customer and PAB reserve computations is appropriate in the

public interest, and is consistent with the protection of investors.

In particular, it is appropriate to permit Clearing Members to include an Item 13 debit in the customer and PAB reserve computations for margin required and on deposit at CCUS for customer binary options. Without the availability of an Item 13 debit, increases in the amounts of required customer margin as a result of the clearance of binary options at CCUS would result in corresponding increases in the need for Clearing Members to use their own cash and securities to meet CCUS customer margin requirements. This relief also may avoid potential increases in a Clearing Member's required deposits in its special reserve bank accounts (because there is no permitted Item 13 debit for CCUS to offset credits).²⁷ This relief would also help to reduce any capital constraints and inefficiencies for Clearing Members, which may affect their liquidity and reduce their willingness to intermediate customer access to cleared binary options at CCUS. Additionally, it is in the public interest to permit an Item 13 debit to help promote competition in the development of a cleared securities market for trading binary security options of the type anticipated to be cleared by CCUS and facilitate access to the central clearing and settlement of securities options.

Further, the Commission adopted amendments to Rule 15c3–3a to add the Item 13 debit in 1977, when the OCC was the only clearing agency registered with the Commission that provided central counterparty services for options contracts.²⁸ The rule's specific reference to OCC therefore identifies the single qualifying clearing agency that existed at that time. However, circumstances have changed. CCUS has been approved as a second clearing agency for options.²⁹ Providing this relief will help ensure that the same margin treatment under the Item 13 debit applies to both CCUS and OCC, and to their broker-dealer members, thereby facilitating fair competition among Commission-registered options clearing agencies which is in the public interest. Finally, permitting the Item 13 debit for CCUS will support a broker-dealer's customer facilitation activity in securities options

¹⁶ 15 U.S.C. 78q–1(a)(2).

¹⁷ See Application at 4.

¹⁸ Item 14 of the customer reserve computation is a debit item for margin that is required and on deposit with a registered clearing agency under section 17A of the Exchange Act (15 U.S.C. 78q–1), or a derivatives clearing organization (“DCO”) registered with the Commodity Futures Trading Commission (“CFTC”) under section 5b of the Commodity Exchange Act (“CEA”) (7 U.S.C. 7a–1) related to positions written, purchased or sold in customer accounts with respect to security futures products, and futures contracts (and options thereon) carried in a securities account pursuant to a self-regulatory organization (“SRO”) margining rule. See 17 CFR 240.15c3–3a, Item 14.

¹⁹ Item 15 of the customer reserve computation is a debit item for margin required and on deposit with a clearing agency registered with the Commission under section 17A of the Exchange Act resulting from specified transactions in U.S. Treasury securities in customer accounts that have been cleared, settled and novated by the clearing agency. See 17 CFR 240.15c3–3a, Item 15.

²⁰ See Application at 4–5.

²¹ See *id.*

²² See *id.*

²³ See Application at 2–3. CCUS's margin requirements for binary options, discussed in Exhibit J to its Form CA–1 application seeking temporary registration and known as its “margin model,” are contained in its Margin Model and Stress Scenarios document (Ex. E–1.86 to Form CA–1).

²⁴ See Application at 5.

²⁵ See Application at 3–4.

²⁶ 15 U.S.C. 78mm(a)(1).

²⁷ See section I.B. (discussing customer reserve computation and special reserve bank account).

²⁸ See *Uniform Net Capital Rule and Customer Protection Rule; Final Rule*, Exchange Act Release No. 13565 (May 23, 1977), 42 FR 27221 (May 27, 1977).

²⁹ See CCUS Temporary Registration Order, *supra* note 3.

clearing, in light of the increased number of securities clearing agencies.

The conditions in this order, discussed below in section I.B, are designed to permit the Item 13 debit only in circumstances that provide protections to customers consistent with the customer protection objectives of Rules 15c3-3 and 15c3-3a and the current approach for margin required and on deposit at OCC. For example, Rule 15c3-3 requires broker-dealers to take steps to safeguard customer assets by segregating their securities and cash from the carrying broker-dealer's proprietary business activities.³⁰ The conditions in this order are designed to ensure that customer margin is appropriately segregated and that a broker-dealer cannot use customer cash and securities to finance its proprietary business activities. Further, consistent with the existing Item 13 debit for margin required and on deposit at OCC, the conditions of this order explicitly limit the exemption to customer margin required and deposit with CCUS with respect to customer positions in binary options. These conditions help reduce the likelihood of certain risks that may undermine the customer protection objectives of Rule 15c3-3, including that broker-dealers may not appropriately safeguard customer cash and securities or may improperly include debits in their customer reserve computation.

The one comment letter that the Commission received on the Notice of an Application generally supported the request for an exemption,³¹ but recommended that the Commission impose additional conditions in connection with granting the request. Specifically, the commenter pointed to the conditions contained in Note G to the Item 14 debit related to margin required and on deposit at a registered clearing agency for security futures products and futures contracts, as well as Note H to the Item 15 debt related to margin required and on deposit at a registered clearing agency for transactions in Treasury securities and recommended that the Commission impose the conditions therein on CCUS in connection with the requested exemption to the extent that such conditions "fit" binary options.³² The Commission has considered the comment letter, and is declining to incorporate the suggested conditions. The conditions proposed by CCUS, and outlined below, are robust and

reasonably designed to protect investors.

Accordingly, after careful consideration of the Application and the comment received, the Commission is issuing, pursuant to section 36(a)(1) of the Exchange Act, conditional exemptive relief to exempt Clearing Members from the limitation in Item 13 and Note F of Rule 15c3-3a that confines the Item 13 debit to the amount of margin required and on deposit with the OCC, and as such, Clearing Members may include a debit in Item 13 of their customer and PAB reserve computations for margin required and on deposit with CCUS for all binary options contracts written or purchased in customer accounts, subject to the conditions discussed below.

B. Discussion of Conditions

The first condition provides that CCUS must be registered with the Commission as a clearing agency in accordance with section 17A(b)³³ of the Exchange Act and Rule 17ab2-1³⁴ thereunder. This condition is designed to ensure that the relief provided in this order remains consistent with the customer protection objectives of Rule 15c3-3, and specifically those provided by the limitations in Item 13 and Note F of Exhibit A to Rule 15c3-3, by ensuring that CCUS operates subject to the same regulatory framework as the OCC, which is a registered clearing agency.³⁵

The second condition requires that the relief provided by this order will apply solely to margin required and on deposit with CCUS with respect to customer positions in binary options. This condition is designed to ensure that the relief provided is limited to only margin applicable to options transactions in customer accounts, the same type of transactions covered under Item 13 of Rule 15c3-3a. This condition also will ensure that margin required and on deposit at CCUS as a result of a Clearing Member's proprietary positions may not be included as a debit in the reserve computations. Therefore, this condition is designed to effectuate a fundamental aspect of Rule 15c3-3 that a broker-dealer cannot use customer cash or securities to finance its proprietary business activities.

The third condition provides that the binary options that CCUS clears will be margined by CCUS consistent with the requirements of Rule 17Ad-22(e) and

Clearing Members will collect such margin from their customers, with any proposed changes to CCUS's margin system subject to Commission review, and, as appropriate, approval pursuant to section 19(b) of the Exchange Act and Rule 19b-4 thereunder. CCUS has stated that the binary options will be fully margined at the clearing agency level.³⁶ This condition ensures that the Clearing Members hold sufficient customer collateral to cover the required margin amounts at CCUS, and that proposed changes to CCUS's margin system would need to be filed with the Commission through a rule filing under section 19(b) of the Exchange Act. The purpose of this condition is to help ensure that the exemption provided under this order is only available when regulatory requirements are appropriately followed.

The fourth condition requires that, for the purposes of Rule 15c3-3a, CCUS will maintain margin required and on deposit with CCUS for binary options contracts written or purchased in customer accounts separately and independently from margin required and on deposit for proprietary positions of Clearing Members. This condition will increase customer protection by ensuring that customer margin is clearly identifiable and segregated from margin related to the Clearing Member's proprietary positions.³⁷ In doing so, this condition, similar to the second condition, is designed to further effectuate the fundamental aspect of Rule 15c3-3 that prohibits a broker-dealer from using customer cash or securities to finance its proprietary business activities.

The fifth condition limits the scope of relief provided by this order to the same conditions set forth in Note F to Item 13 of Rule 15c3-3a that apply to margin required and on deposit with OCC for all option contracts written or purchased in customer accounts. Specifically, Note F to Item 13 states that Item 13 must include the amount of margin required and on deposit with the OCC to the extent such margin is represented by cash, proprietary qualified securities and letters of credit collateralized by customers' securities. This condition is thus designed to protect investors by ensuring that

³⁶ Broker-dealers are also subject to margin requirements in rules promulgated by the Federal Reserve (12 CFR 220.1, *et seq.*) and SROs (*see, e.g.*, FINRA Rule 4210 and Cboe Rule 10.3).

³⁷ *See, e.g.*, OCC By-Laws, Article 1 (Definitions) (defining the term "customers' account" in respect of a Clearing Member to mean "an account of the Clearing Member on the records of the Corporation which is confined to confirmed trades cleared and positions carried by the Clearing Member on behalf of its securities customers . . .").

³⁰ *See* section I.B. of this order.

³¹ *See* letter from Shawn SN, at 2.

³² *Id.* at 2-3 and 11-15.

³³ 15 U.S.C. 78q-1.

³⁴ 17 CFR 240.17ab2-1.

³⁵ A list of registered clearing agencies is available at: <https://www.sec.gov/rules-regulations/self-regulatory-organization-rulemaking>.

Clearing Members can only include the Item 13 debit where they deposit with CCUS the full amount of margin required for all binary options contracts written or purchased in customer accounts. Further, this condition will ensure the permitted debit under Item 13 will remain limited to the same scope of assets that are permissible to use as collateral delivered to the OCC under Note F to Rule 15c3–3a, to remain consistent with established customer protections under the rule.

The sixth condition states that the rules of CCUS must have been amended, as necessary to reflect the conditions of this order. This condition is designed to require that Clearing Members may only include an Item 13 debit in their reserve computations pursuant to this order where the rules of CCUS have been amended to conform to the conditions of this exemptive order. This will also ensure that the rules of CCUS that are amended in accordance with the conditions of this order adequately implement the customer protection objectives of Rule 15c3–3 and Rule 15c3–3a.

For the reasons discussed above, the Commission finds that granting Clearing Members conditional exemptive relief from the limitation in Item 13 and Note F to Rule 15c3–3a that confines the Item 13 debit to the amount of margin required and on deposit with the OCC for all option contracts written or purchased in customer accounts is appropriate in the public interest, and consistent with the protection of investors.

III. Conclusion

Accordingly, *it is hereby ordered* pursuant to section 36(a)(1) of the Exchange Act, Clearing Members are exempt from the limitation in Item 13 and Note F of Rule 15c3–3a that confines the Item 13 debit to the amount of margin required and on deposit with the OCC for all option contracts written or purchased in customer accounts, and as such, Clearing Members may include a debit in Item 13 of their customer and PAB reserve computations for margin required and on deposit with CCUS for all binary options contracts written or purchased in customer accounts, subject to the following conditions:

1. *Registration*: CCUS is registered with the Commission as a clearing agency in accordance with section 17A(b) ³⁸ of the Exchange Act and Rule 17ab2–1 ³⁹ thereunder.

2. *Eligibility Limitation*: The relief will apply solely to margin required and on

deposit with CCUS with respect to customer positions in binary options.

3. *Margined Customer Positions*: The binary options that CCUS clears will be margined by CCUS consistent with the requirements of Rule 17Ad–22(e) ⁴⁰ and Clearing Members will collect such margin from their customers, with any proposed changes to CCUS's margin system subject to Commission review, and, as appropriate, approval pursuant to section 19(b) ⁴¹ of the Exchange Act and Rule 19b–4 ⁴² thereunder.

4. *Segregation of Customer Margin*: For purposes of Rule 15c3–3a, CCUS will maintain margin required and on deposit with CCUS for binary options contracts written or purchased in customer accounts separately and independently from margin required and on deposit for proprietary positions of Clearing Members.

5. The relief would be subject to the same conditions set forth in Note F to Item 13 of Rule 15c3–3a that apply to margin required and on deposit with OCC for all option contracts written or purchased in customer accounts.

6. The rules of CCUS must have been amended to reflect the conditions of this order.

By the Commission.

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2026–21931 Filed 10–27–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0617]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Rule 433

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Rule 433 (17 CFR 230.433) governs the use and filing of free writing prospectuses with respect to the securities of an issuer that are the subject of a registration statement that has been filed under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*). A free writing prospectus that satisfies the

conditions pursuant to Rule 433 will be a prospectus under Section 10(b) of the Securities Act and will be deemed to be public without regard to its method of use or distribution. Rule 433 is intended to facilitate issuer communications during a registered offering of securities after a registration statement has been filed with the Commission. The information filed under Rule 433 is mandatory, and filings made pursuant to Rule 433 are publicly available on the Commission's Electronic Data Gathering, Analysis, and Retrieval (“EDGAR”) system. We estimate that there are approximately 20,179 free writing prospectuses filed pursuant to Rule 433 annually, for a total of approximately 20,179 responses annually. We estimate that respondents incur approximately 2.45 burden hours per Rule 433 response, for a total annual reporting burden of 49,439 hours (2.45 hours per response × 20,179 responses). We estimate that respondents incur \$380.03 cost burden per Rule 433 response, for a total annual cost of \$7,668,625 (\$380.03 cost per response × 20,179 responses).

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 public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202607-3235-025 or send an email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice by November 30, 2026.

Dated: October 26, 2026.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026–22000 Filed 10–27–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106727; File No. SR–MEMX–2026–33]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 11.15 (Clearly Erroneous Executions)

October 23, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,²

³⁸ 15 U.S.C. 78q–1.

³⁹ 17 CFR 240.17ab2–1.

⁴⁰ 17 CFR 240.17ad–22(e).

⁴¹ 15 U.S.C. 78s.

⁴² 17 CFR 240.19b–4.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

notice is hereby given that on October 19, 2026, MEMX LLC (“MEMX” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend Rule 11.15 (“Clearly Erroneous Executions”) in light of the Commission’s approval of Overnight Protected Bands for 3/5 Trading. The proposal is similar to a proposal that NYSE American filed with the Commission.⁵ The text of the proposed rule change is provided in Exhibit 5 and is available on the Exchange’s website at <https://info.memxtrading.com/regulation/rules-and-filings/>.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.15 (“Clearly Erroneous Executions”) in light of the Commission’s approval of Overnight Protected Bands under the LULD Plan for 23/5 Trading.

Background

In September 2026, the Exchange filed for immediate effectiveness a proposal to introduce trading 23 hours a day, 5 days a week (“23/5 Trading”).⁶ As part of that proposal, the Exchange made changes to Rule 11.15 (“Clearly Erroneous Executions”) to treat transactions executed during the Overnight Trading Session in the same manner as transactions executed during the Pre-Market and Post-Market Sessions.

Subsequently, the Operating Committee of the Plan to Address Extraordinary Market Volatility (“LULD Plan”) filed proposed Amendment 27 to the LULD Plan, which proposed to establish price band protections during overnight trading hours (“Overnight Price Bands”).⁷ The Operating Committee proposed that the Overnight Price Bands would initially be temporary static bands 20% above and below two reference points, and that after implementation, the Operating Committee would evaluate the performance of such Overnight Price Bands and propose appropriate changes in a new plan amendment.⁸ On August 5, 2026, the Commission approved the proposal.⁹

In light of the Commission’s approval of these changes to the LULD Plan, the Exchange now proposes to reverse the changes to Rule 11.15 that were made as part of the MEMX 23/5 Filing, and to make several other amendments to Rule 11.15 in light of the Commission’s approval of Overnight Price Bands.

In general, Rule 11.15 describes the process a market participant may use to request cancellation of a transaction that was “clearly erroneous.” The current rule’s central premise is that if LULD Price Bands under the LULD Plan were available and correct at the time the transaction was executed, the transaction is not eligible for clearly erroneous review. Specifically, Rule 11.15(c)(1) currently provides that “[i]f the execution time of the transaction(s) under review is during Regular Trading Hours, the transaction will not be reviewable as clearly erroneous” except

in certain limited circumstances, including when (A) the transaction is in an NMS stock that is not subject to the LULD Plan (e.g., rights and warrants), (B) the transaction was executed at a time when LULD Price Bands were unavailable or trading should have been prevented due to a regulatory halt or other halt, or (C) several other limited circumstances.¹⁰ In approving the existing version of the rule, the Commission noted that restricting clearly erroneous review in this way during times when LULD Price Bands were in effect was “consistent with the Act and will further the goal of providing greater certainty to market participants that trades executed within the Price Bands will stand and not be broken. . . . Thus, the proposal is designed to limit the potential discordance between the LULD mechanism and CEE review process.”¹¹

Currently, LULD Price Bands are available only during Regular Trading Hours, meaning that the restrictions on clearly erroneous review described above apply only during Regular Trading Hours. With the introduction of Overnight Price Bands, the Exchange now proposes to extend the existing restrictions on clearly erroneous review to the period when Overnight Price Bands are in place. This proposed change would be consistent with the Commission’s rationale in approving the current version of the rule because it would limit any potential discordance between the LULD mechanism and CEE review in the overnight trading session, providing greater certainty to market participants that trades executed with the Overnight Price Bands will stand and not be broken.

Reversal of Changes Made to Rule 11.15

As noted above, as part of the MEMX 23/5 Filing,¹² the Exchange made changes to Rule 11.15 to treat transactions executed during the Overnight Trading Session in the same manner as transactions executed during the Pre-Market and Post-Market Sessions. Given the Commission’s subsequent approval of Overnight Price Bands, the Exchange proposes to reverse each of the changes made to Rule 11.15 by the MEMX 23/5 Filing.¹³ As detailed

⁶ See Securities Exchange Act Release No. 106310 (September 9, 2026) 91 FR 58185 (September 14, 2026) (SR-MEMX-2026-28) (“MEMX 23/5 Filing”).

⁷ See Securities Exchange Act Release No. 105596 (June 1, 2026), 91 FR 33774 (June 4, 2026) (File No. 4-631) (Notice of Filing of 27th Amendment to the National Market System Plan).

⁸ See *id.*

⁹ See Securities Exchange Act Release No. 106042 (August 5, 2026), 91 FR 51515 (August 10, 2026) (File No. 4-631) (Order Granting Approval of the 27th Amendment to the National Market System Plan to Address Extraordinary Market Volatility to Establish Temporary Price Band Protections in Overnight Trading).

¹⁰ See Rule 11.15(c)(1)(A), (B), and (C).

¹¹ See Securities Exchange Act Release No. 95658 (September 1, 2022), 87 FR 55060 at 55063 (September 8, 2022) (SR-ChoeBZX-2022-037) (Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, to Amend BZX Rule 11.17, Clearly Erroneous Executions).

¹² See MEMX 23/5 Filing, *supra* note 6.

¹³ Specifically, the Exchange proposes reversing the changes made by the MEMX 23/5 Filing to Rule 11.15(c)(2)(A)-(D), (d)(3), and (f).

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4.

⁵ See Securities Exchange Act Release No. 106315 (September 9, 2026) 91 FR 58201 (September 14, 2026) (SR-NYSEAMER-2026-80).

below, this proposal would instead make clearly erroneous review of transactions executed during the Overnight Trading Session available in a manner similar to transactions executed during Regular Trading Hours.

Proposed Changes to Rule 11.15(c)(1)

To implement this change, the Exchange proposes to add several definitions to Rule 11.15(c)(1). First, the Exchange would add that the term “LULD Protected Hours” includes Regular Trading Hours and “Overnight Protected Hours” defined in Section VIII of the LULD Plan. Second, the Exchange would define “LULD Price Bands” or “Price Bands” to mean the Price Bands defined in Section V of the LULD Plan (*i.e.*, the Price Bands that apply during Regular Trading Hours) and “Overnight Price Bands” as defined in Section VIII of the LULD Plan (*i.e.*, the Price Bands that apply to the Overnight Protected Hours from 9:00 p.m. ET through 4:00 a.m. ET).

The Exchange proposes to amend the current first sentence of Rule 11.15(c)(1) to replace the phrase “Regular Trading Hours” with “LULD Protected Hours,” to provide that “[i]f the execution time of the transaction(s) under review is during LULD Protected Hours, the transaction will not be reviewable as clearly erroneous” This change would extend the LULD-based restrictions on clearly erroneous review currently in place during Regular Trading Hours to the Overnight Protected Hours.

The Exchange also proposes to amend Rule 11.15(c)(1)(B)’s reference to “Percentage Parameter” to incorporate the Percentage Parameter that applies to Overnight Protected Hours. The amended provision would provide for the applicability of clearly erroneous review if the price of the transaction to buy (sell) that is the subject of the clearly erroneous complaint is greater than (less than) the Reference Price by an amount that equals or exceeds the applicable Percentage Parameter defined in Appendix A to the LULD Plan (with respect to the Price Bands that apply during Regular Trading Hours) or the “Overnight Percentage Parameter defined in Section VIII of the LULD Plan” (with respect to Overnight Protected Hours).

In addition to these changes, the Exchange also proposes to make a non-substantive change to Rule 11.15(c)(1)(A), substituting the term “LULD Plan” for the current text “the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ‘Limit Up-Limit Down Plan’ or ‘LULD

Plan,)” as the “LULD Plan” would be defined in the proposed revision to Rule 11.15(c)(1).

Proposed Changes to Rule 11.15(c)(2), (d)(3), and (f)

As noted above, current Rule 11.15(c)(1)(A) permits clearly erroneous review even during Regular Trading Hours when the transaction in question is in an NMS Stock that is not subject to the LULD Plan, *i.e.*, rights and warrants. Such transactions are reviewed for clearly erroneous status using the procedures set out in Rule 11.15(c)(2), including the Numerical Guidelines set out in the table accompanying Rule 11.15(c)(2)(A). The Exchange now proposes to introduce a similar provision regarding transactions in NMS Stocks not subject to the LULD Plan that are executed during the Overnight Protected Hours; such transactions would be subject to the same Numerical Guidelines as transactions occurring in the Pre-Market and Post-Market Sessions.

The heading of Rule 11.15(c)(2) currently addresses, in part, the “[r]eview of transactions occurring during Overnight Trading Session, Pre-Market Session, Post-Market Session, or eligible for review pursuant to paragraph (c)(1)(A).” The Exchange proposes to remove the reference to the Overnight Trading Session that was added by the MEMX ²³/₅ Filing. The Exchange also proposes to replace the phrase “eligible for review pursuant to paragraph (c)(1)(A)” (which, in the current rule, means transactions executed during Regular Trading Hours in NMS Stocks not subject to the LULD Plan) with “during LULD Protected Hours in NMS Stocks not subject to the LULD Plan.” This proposed language would cover transactions in NMS Stocks not subject to the LULD Plan in Regular Trading Hours and expand the same treatment to transactions executed in NMS Stocks not subject to the LULD Plan during Overnight Protected Hours. As such, the proposed change is not novel.

The Exchange proposes to make the same changes everywhere else such language appears in the rule—namely, in the text of paragraphs (c)(2)(A), (c)(2)(B), (c)(2)(C), (c)(2)(D), (d)(3), and (f).¹⁴ In each case, the Exchange

proposes to remove the reference to the Overnight Trading Session added by the MEMX ²³/₅ Filing and to replace the phrase “eligible for review pursuant to paragraph (c)(1)(A)” with “during LULD Protected Hours in NMS Stocks not subject to the LULD Plan.”

The Exchange also proposes to make corresponding changes to the headings of the table accompanying Rule 11.15(c)(2)(A). The Exchange proposes to change the heading of the second column from “Regular Trading Hours Numerical Guidelines for transactions eligible for review pursuant to paragraph (c)(1)(A)” to “Numerical Guidelines for Transactions Executed During Regular Trading Hours in NMS Stocks Not Subject to the LULD Plan.” This change would simply replace the shorthand “eligible for review pursuant to paragraph (c)(1)(A)” with the fuller description that such transactions are “executed during Regular Trading Hours in NMS Stocks not subject to the LULD Plan,” and is not a substantive change.

Similarly, the Exchange proposes to change the heading of the third column from “Overnight Trading, Pre-Market and Post-Market Session Numerical Guidelines” to “Numerical Guidelines for Transactions Executed During the Pre-Market and Post-Market Session or During Overnight Protected Hours in NMS Stocks Not Subject to the LULD Plan.” The proposed change removes the reference to the Overnight Trading Session added by the MEMX ²³/₅ Filing and addresses the fact that transactions executed during Overnight Protected Hours in NMS Stocks not subject to the LULD Plan are eligible for clearly erroneous review—just as are transactions in NMS Stocks not subject to the LULD Plan executed during Regular Trading Hours—but at the Numerical Guidelines that apply outside of Regular Trading Hours.

Together, these proposed changes would extend the eligibility of clearly erroneous review for transactions in NMS Stocks not subject to the LULD Plan that is currently in place during Regular Trading Hours to the Overnight Protected Hours, and would apply the Commission’s recent approval of Overnight Price Bands to the clearly erroneous executions rule.

Implementation

The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals, the substance of which are identical to

¹⁴ Rule 11.15(c)(2)(A)–(D) specifies general rules for applying clearly erroneous review to transactions where such review is not precluded by paragraph (c)(1). Rule 11.15(d)(3) specifies conditions where the Exchange may use a revised Reference Price for the purpose of clearly erroneous review in certain transactions where such review is not precluded by paragraph (c)(1). Rule 11.15(f) specifies that for transactions where clearly

erroneous review is not precluded by paragraph (c)(1), an officer may initiate clearly erroneous review on his or her own motion.

this proposal. The Exchange proposes that this rule change would become operative at the commencement of ²³/₅ Trading, which is scheduled to commence industry-wide on December 6, 2026.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹⁵ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁶ requirements that the rules of an exchange promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change is consistent with just and equitable principles of trade because it extends the basic premise of the current rule that clearly erroneous review should be generally unavailable any time a transaction is executed within LULD Price Bands at a time the Price Bands were available and correct. Currently, LULD Price Bands are available only during Regular Trading Hours, meaning that the restrictions on clearly erroneous review described above apply only during Regular Trading Hours. With the Commission's approval of Overnight Price Bands, the Exchange believes that reversing the changes made to the rule by the MEMX ²³/₅ Filing and extending the current restrictions on clearly erroneous review to the period when Overnight Price Bands are in place would remove impediments to and perfect the mechanism of a free and open market and a national market system by enhancing the transparency and consistency of the rule.

The resulting rule would thus extend the LULD-related limits on clearly erroneous review that are applicable in Regular Trading Hours to the overnight period. The proposed change would also be consistent with the Commission's rationale in approving the current version of the rule because it would limit any potential discordance between the LULD mechanism and CEE review in the overnight trading session, providing greater certainty to market participants that trades executed with

the Overnight Price Bands will stand and not be broken.¹⁷

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather than impacting competition, the proposed change would simply extend the basic premise of the current rule that clearly erroneous review should be generally unavailable any time a transaction is executed within LULD Price Bands at a time the Price Bands were available and correct. The Exchange understands that the other national securities exchanges and FINRA will also file similar proposals, the substance of which are identical to this proposal. Thus, the proposed rule change will help to ensure consistency across SROs without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁸ and Rule 19b-4(f)(6)¹⁹ thereunder.

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule

change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-MEMX-2026-33 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-MEMX-2026-33. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-MEMX-2026-33 and should be submitted on or before November 18, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2026-21926 Filed 10-27-26; 8:45 am]

BILLING CODE 8011-01-P

¹⁷ See 87 FR 55060 at 55063, *supra* note 11.

¹⁸ 15 U.S.C. 78s(b)(3)(A).

¹⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

²⁰ 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78f(b).

¹⁶ 15 U.S.C. 78f(b)(5).

SECURITIES AND EXCHANGE COMMISSION

[OMB Control No. 3235–0619]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension: Rule 163

Upon Written Request, Copies Available

From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget this request for extension of the previously approved collection of information discussed below.

Rule 163 (17 CFR 230.163) provides an exemption from Section 5(c) of the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) for certain communications by, or on behalf of, a well-known seasoned issuer, as defined in Rule 405 (17 CFR 230.405), before a registration statement is filed, subject to certain conditions. The rule is intended to facilitate capital formation by giving eligible well-known seasoned issuers freedom to communicate with investors at any time, including by means of a written offer other than a statutory prospectus. The information filed under Rule 163 is mandatory, and filings made pursuant to Rule 163 are publicly available on the Commission’s Electronic Data Gathering, Analysis, and Retrieval (“EDGAR”) system. We estimate that approximately 12 respondents make one filing per year pursuant to Rule 163, for a total of approximately 12 responses annually. We estimate that respondents incur approximately 0.083 hours per Rule 163 response, for a total annual reporting burden of 1 hour (0.083 hours per response × 12 responses). We estimate that respondents incur \$72.50 cost burden per Rule 163 response, for a total annual cost of \$870 (\$72.50 cost per response × 12 responses).

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 public may view and comment on this information collection request at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202607-3235-021 or send an email comment to MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov within 30 days of the day after publication of this notice by November 30, 2026.

Dated: October 26, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–22005 Filed 10–27–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–106725; File No. SR–NYSETEX–2026–30]

Self-Regulatory Organizations; NYSE Texas, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Offer Complimentary Products and Services

October 23, 2026.

I. Introduction

On August 13, 2026, NYSE Texas, Inc. (“NYSE Texas” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”), pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b–4 thereunder, ³ a proposed rule change to adopt new Rule 24 under Article 22 of the NYSE Texas Rule Book to offer certain issuers complimentary products and services from the Exchange. The proposed rule change was published for comment in the *Federal Register* on September 1, 2026. ⁴ On October 5, 2026, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the original filing in its entirety. ⁵ The Commission has received no comment letters on the proposal. The Commission is publishing this notice and order to solicit comments on Amendment No. 1 from interested persons and to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ See Securities Exchange Act Release No. 106204 (Aug. 27, 2026), 91 FR 56247 (“Notice”).

⁵ In Amendment No. 1 to the proposed rule change, the Exchange: (i) clarified that the visibility and investment engagement products and services will be offered on a one-time basis; (ii) provided additional description and support for certain aspects of the proposal; and (iii) made minor technical changes to improve the clarity and readability of the proposed rule change. Amendment No. 1 is available on the Commission’s website at: <https://www.sec.gov/rules-regulations/public-comments/sr-nysetex-2026-30> (“Amendment No. 1”).

II. Description of Proposed Rule Change, as Modified by Amendment No. 1

The Exchange is proposing to adopt Rule 24 under Article 22 of the NYSE Texas Rule Book to offer complimentary services to certain issuers listed on the Exchange. First, the Exchange proposes to codify in new Rule 24 that all issuers listed on the Exchange are entitled to certain services, including use of the Exchange’s headquarters in Dallas, Texas, on a complimentary basis as described on the Exchange’s website. ⁶ The Exchange states that it offers these complimentary services to all issuers without regard to size or any other factor. ⁷

Second, the Exchange proposes to define as an “Eligible Dual Listing” any U.S. or any non-U.S. company (i) whose primary class of equity securities is listed on another national securities exchange and is listing such class of securities on the Exchange as a dual listing pursuant to Rule 18 of the NYSE Texas Rule Book; and (ii) that has 160 million or more total shares of common stock issued and outstanding in all share classes, including and in addition to treasury shares (a non-U.S. company must have 160 million or more shares of an equity security issued and outstanding in the U.S.). ⁸ The Exchange will offer an Eligible Dual Listing a one-time package of visibility and investor engagement products and services with a commercial value of approximately \$50,000. ⁹ The Exchange states that the package of visibility and investor engagement products and services would entitle an Eligible Dual Listing to hold an investor meeting at the Exchange’s headquarters in Dallas, Texas and a marketing activation to publicize the issuer’s dual listing on the Exchange or other corporate developments. ¹⁰

III. Discussion and Commission Findings

After careful review, the Commission finds the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of Section 6 of the Act. ¹¹ Specifically, the

⁶ See *id.* at 4.

⁷ See *id.*

⁸ See *id.*

⁹ See *id.*

¹⁰ See *id.* The Exchange states that Eligible Dual Listings may elect to receive some or all of the products and services for which they are eligible but are under no obligation to accept any such product or service, and a determination not to accept such services will have no effect on an issuer’s continued listing on the Exchange. See *id.* at 4, 5.

¹¹ 15 U.S.C. 78f. In approving this proposed rule change, the Commission has considered the

Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Sections 6(b)(4) and 6(b)(5) of the Act,¹² in particular, in that the proposed rule is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among Exchange members, issuers, and other persons using the Exchange's facilities, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Moreover, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(8) of the Act¹³ in that it does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The proposal to codify the Exchange's current offering of certain complimentary services to all issuers and to offer a one-time package of visibility and investor engagement products and services on a complimentary basis to certain issuers, as described above,¹⁴ is appropriate and consistent with the Act. Describing in the Exchange's rules the services available to listed companies, their associated values, and the length of time for which issuers are entitled to receive such services adds greater transparency to the Exchange's rules and will help to ensure that individual listed companies are not given specially negotiated packages of products or services to list, or remain listed, which would raise unfair discrimination issues under the Act.¹⁵ All listed companies will receive the complimentary services, including the use of the Exchange's headquarters, described on the Exchange's website. Further, the Exchange represents that offering the proposed complimentary services will not adversely affect the funding available for the Exchange's regulatory responsibilities.¹⁶ Accordingly, the Exchange will continue to be able to allocate sufficient

resources to, and fully perform, all its regulatory obligations.

Section 6(b)(5) of the Act does not require that all issuers be treated the same; rather, the Act requires that the rules of an exchange not unfairly discriminate between issuers.¹⁷ The Commission has previously found that offering certain complimentary products and services to issuers that meet specified criteria was consistent with the Act.¹⁸ The Exchange states that it proposes to offer a one-time package of visibility and investor engagement products and services to issuers that have at least 160 million shares outstanding, as opposed to issuers with fewer shares outstanding, as they tend to be larger companies with a larger and more diversified shareholder base and thus have greater demand for visibility and engagement.¹⁹ Additionally, the Exchange states that other exchanges offer complimentary products and services to issuers on a tiered basis based on shares outstanding.²⁰ For these reasons, the Commission finds that the complimentary services set forth in the proposed rule change, as modified by Amendment No. 1, are equitably allocated among issuers consistent with Section 6(b)(4) of the Act and do not unfairly discriminate between issuers consistent with Section 6(b)(5) of the Act.

The Exchange is responding to competitive pressures in the market for listings in making this proposal. The Exchange states that it recently reincorporated in the State of Texas and that issuers are increasingly interested in developing a presence in Texas.²¹ The Exchange also states that offering complimentary services will facilitate issuer engagement with investors and entice issuers to dually list on the Exchange.²² The Commission understands that the Exchange faces competition in the market for listing

services, and that it may compete in part by providing complimentary services to its listed companies. Accordingly, the Commission finds that the proposed rule change, as modified by Amendment No. 1, reflects the current competitive environment for exchange listings among national securities exchanges, and is appropriate and consistent with Section 6(b)(8) of the Act.²³

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSETEX-2026-30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSETEX-2026-30. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSETEX-2026-30 and should be submitted on or before November 18, 2026.

V. Accelerated Approval of the Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of

proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹² 15 U.S.C. 78f(b)(4) and (b)(5).

¹³ 15 U.S.C. 78f(b)(8).

¹⁴ See *supra* notes 6-9 and accompanying text.

¹⁵ The Commission views complimentary products and services provided by exchanges to listed companies as a discount on the ultimate listing fees paid by such companies. See, e.g., Securities Exchange Act Release Nos. 79366 (Nov. 21, 2016), 81 FR 85663 (Nov. 28, 2016) (SR-NASDAQ-2016-106) ("Nasdaq 2016 Approval Order"); 81872 (Oct. 13, 2017), 82 FR 48733 (Oct. 19, 2017) (SR-IEEX-2017-20); 65963 (Dec. 15, 2011), 76 FR 79262 (Dec. 21, 2011) (SR-NASDAQ-2011-122) ("Nasdaq 2011 Approval Order"); and 65127 (Aug. 12, 2011), 76 FR 51449 (Aug. 18, 2011) (SR-NYSE-2011-20) ("NYSE 2011 Approval Order").

¹⁶ See Amendment No. 1, *supra* note 5, at 5.

¹⁷ 15 U.S.C. 78f(b)(5). See also Securities Exchange Act Release No. 98367 (Sept. 12, 2023), 88 FR 64016 (Sept. 18, 2023) (SR-NASDAQ-2023-017); Nasdaq 2016 Approval Order at 85665; Nasdaq 2011 Approval Order at 79266; NYSE 2011 Approval Order at 51452.

¹⁸ See Securities Act Release No. 94222 (Feb. 10, 2022), 87 FR 8886 (Feb. 16, 2022) (SR-NYSE-2021-68); NYSE 2011 Approval Order at 51452.

¹⁹ See Amendment No. 1, *supra* note 5, at 5.

²⁰ See *id.* (citing Section 907.00 of the NYSE Listed Company Manual, which provides that NYSE will offer ongoing complimentary products and services to issuers with at least 160 million shares outstanding).

²¹ See Amendment No. 1, *supra* note 5, at 4, 5.

²² See *id.* at 5. The Exchange states that Nasdaq Texas, LLC recently adopted a package of complimentary services offered to issuers dually listed on its exchange. See *id.* (citing Securities Exchange Act Release No. 105883 (July 10, 2026), 91 FR 43408 (July 15, 2026) (SR-NasdaqTX-2026-025)).

²³ 15 U.S.C. 78f(b)(8).

publication of notice of the filing of Amendment No. 1 in the **Federal Register**. Amendment No. 1 sets forth additional support and clarifying details regarding the proposal. These changes (1) clarified that the visibility and investment engagement products and services will be offered on a one-time basis; (2) provided additional description and support for certain aspects of the proposal; and (3) made minor technical changes to improve the clarity and readability of the proposed rule change. Amendment No. 1 does not alter any substantive provisions of the remaining parts of the proposed rule change, or raise any regulatory issues substantially different from what is set forth in the Notice, which was subject to public comment.²⁴ Further, the changes and additional discussion in Amendment No. 1 assist the Commission in evaluating the proposal and determining that it is consistent with the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,²⁵ to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,²⁶ that the proposed rule change (SR-NYSETEX-2026-30), as modified by Amendment No. 1, be and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁷

J. Matthew DeLesDernier,
Deputy Secretary.

[FR Doc. 2026-21925 Filed 10-27-26; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21991; COLORADO Disaster Number CO-20038 Declaration of Economic Injury]

Administrative Declaration of an Economic Injury Disaster for the State of Colorado

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of an Economic Injury Disaster Loan (EIDL) declaration for the state of Colorado dated October 23, 2026.

²⁴ See *supra* note 4 and accompanying text.

²⁵ 15 U.S.C. 78s(b)(2).

²⁶ *Id.*

²⁷ 17 CFR 200.30-3(a)(12).

Incident: Elk Fire.

DATES: Issued on October 23, 2026.

Incident Period: July 09, 2026 through October 01, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: July 23, 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 Administrator's EIDL declaration, applications for disaster loans may be submitted 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: Hinsdale.

Contiguous Counties:

Colorado: Archuleta, Gunnison, La Plata, Mineral, Ouray, Saguache, San Juan.

The Interest Rates are:

	Percent
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for economic injury is 219910.

The state which received an EIDL declaration is Colorado.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026-21958 Filed 10-27-26; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21966 and #21967; COLORADO Disaster Number CO-20032]

Administrative Declaration Amendment of a Disaster for the State of Colorado

AGENCY: U.S. Small Business Administration.

ACTION: Correction.

SUMMARY: This is a correction to the Administrative declaration of disaster for the State of Colorado dated October 14, 2026.

Incident: Wildfires, Flooding, and Mudslides.

DATES: Issued on October 23, 2026.

Incident Period: June 27, 2026

through July 29, 2026.

Physical Loan Application Deadline Date: December 14, 2026.

Economic Injury (EIDL) Loan

Application Deadline Date: July 14, 2027.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: The notice of the Administrative declaration for the State of Colorado, dated October 14, 2026, published in the **Federal Register** on October 19, 2026 at 91 FR 66191, is hereby corrected to update the incident period for this disaster as beginning June 27, 2026 and continuing through July 29, 2026.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026-21960 Filed 10-27-26; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21988; COLORADO Disaster Number CO-20037 Declaration of Economic Injury]

Administrative Declaration of an Economic Injury Disaster for the State of Colorado

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of an Economic Injury Disaster Loan (EIDL) declaration for the state of Colorado dated October 23, 2026.

Incident: Willow Fire.

DATES: Issued on October 23, 2026.

Incident Period: June 28, 2026

through September 16, 2026.

Economic Injury (EIDL) Loan

Application Deadline Date: July 23, 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 Administrator's EIDL declaration, applications for disaster loans may be submitted 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: Lake.

Contiguous Counties:

Colorado: Chaffee, Eagle, Park, Pitkin, Summit.

The Interest Rates are:

	Percent
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for economic injury is 219880.

The state which received an EIDL declaration is Colorado.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026-21961 Filed 10-27-26; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

[License No. 02020666]

**New Mountain Finance SBIC, L.P.;
Surrender of License of Small
Business Investment Company**

Pursuant to the authority granted to the United States Small Business Administration under Section 309 of the Small Business Investment Act of 1958, as amended, and 13 CFR 107.1900 of the Code of Federal Regulations to function as a small business investment company under the Small Business Investment Company License No. 02020666 issued to New Mountain Finance SBIC, L.P., said license is hereby declared null and void.

Paul Salgado,

*Director, Investment Portfolio Management,
Office of Investment and Innovation.*

[FR Doc. 2026-21955 Filed 10-27-26; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21989 and #21990;
COLORADO Disaster Number CO-20036]

**Administrative Disaster Declaration of
a Rural Area for the State of Colorado**

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of an Administrative disaster declaration of a rural area for the state of Colorado dated October 23, 2026.

Incident: Wildfires, Flooding, and Mudslides.

DATES: Issued on October 23, 2026.

Incident Period: June 27, 2026

through July 29, 2026.

Physical Loan Application Deadline

Date: December 22, 2026.

Economic Injury (EIDL) Loan

Application Deadline Date: July 23, 2027.

ADDRESSES: Visit the MySBA Loan Portal at <https://lending.sba.gov> to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Shaquille Lewis, 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 Administrator's disaster declaration of rural area applications for disaster loans may be submitted online using the MySBA Loan Portal <https://lending.sba.gov> or in person at 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: Ouray.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	5.750
Homeowners without Credit Available Elsewhere	2.875
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
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>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 219895 and for economic injury is 219900.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026-21959 Filed 10-27-26; 8:45 am]

BILLING CODE 8026-09-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21986 and #21987;
PENNSYLVANIA Disaster Number PA-20046]

**Administrative Declaration of a
Disaster for the Commonwealth of
Pennsylvania**

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of an Administrative declaration of a disaster for the Commonwealth of Pennsylvania dated October 23, 2026.

Incident: Severe Storms and Flooding.

DATES: Issued on October 23, 2026.

Incident Period: September 12, 2026 through September 20, 2026.

Physical Loan Application Deadline Date: December 22, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: July 23, 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 Administrator's disaster declaration, applications for disaster loans may be submitted 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: Washington.

Contiguous Counties:

Pennsylvania: Allegheny, Beaver, Fayette, Greene, Westmoreland.

West Virginia: Brooke, Hancock, Marshall, Ohio.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	6.000
Homeowners without Credit Available Elsewhere	3.000
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
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>	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 219866 and for economic injury is 219870.

The states which received an SBA Administrative declaration are Pennsylvania, West Virginia.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery.

[FR Doc. 2026-21967 Filed 10-27-26; 8:45 am]

BILLING CODE 8026-09-P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA-2026-0364]

Privacy Act of 1974; Matching Program

AGENCY: Social Security Administration (SSA).

ACTION: Notice of re-establishment of a matching program.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces the re-establishment of a matching program with the Department of War (DOW), Defense Manpower Data Center (DMDC). Under this matching program, DOW will disclose military retirement payment and survivor benefit payment data to SSA. SSA will use the military retirement payment and survivor benefit payment data to verify information provided by applicants, recipients, deemors (*i.e.*, someone other than the eligible individual or eligible spouse whose income and resources are considered when determining an individual's eligibility for Supplemental Security Income (SSI) and the amount of their payment), and beneficiaries of SSI payments and Special Veterans Benefits (SVB).

DATES: The deadline to submit comments on the proposed matching program is November 27, 2026.

The matching program will be applicable on November 29, 2026, or once a minimum of 30 days after publication of this notice has elapsed, whichever is later. The matching program will be in effect for a period of 18 months.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA-2026-0364 so that we may associate your comments with the correct regulation.

Caution: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at <https://www.regulations.gov>. Use the *Search* function to find docket number SSA-2026-0364 and then submit your comments. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each submission manually. It may take up to a week for your comments to be viewable.

2. *Fax:* Fax comments to (833) 410-1631.

3. *Mail:* Matthew Ramsey, Head of Privacy and Disclosure Policy, Law and Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401, or emailing Matthew.Ramsey@ssa.gov. Comments are also available for public viewing on the Federal eRulemaking portal at <https://www.regulations.gov> or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT:

Interested parties may submit general questions about the matching program to Andrea Huseuth, Division Director, Privacy and Disclosure Policy, Law and Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401, at telephone: (410) 608-9675, or send an email to Andrea.Huseuth@ssa.gov.

SUPPLEMENTARY INFORMATION: This is the reestablishment of a matching program that is set to expire between SSA and DOW, which supports SSA's efficient administration of its SSI and SVB Programs.

Matthew Ramsey,

Head of Privacy and Disclosure Policy, Law and Policy.

PARTICIPATING AGENCIES:

SSA and DOW.

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:

The matching agreement between SSA and DOW is executed in compliance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988, and the regulations and guidance promulgated thereunder.

Legal authority for the disclosure under the agreement for SSA to conduct this matching activity is contained in section 1631(e)(1)(B) and (f) of the Social Security Act (42 U.S.C. 1383(e)(1)(B) and (f)). The legal authority for this exchange is sections 806(b) and 1631(e)(1)(B) and (f) of the Social Security Act (Act) (42 U.S.C. 1006(b) and 1383(e)(1)(B) and (f)). SSA's legal authority to disclose data to DOW is section 1106(a) of the Act (42 U.S.C. 1306(a)) and section (b)(3) of the Privacy Act (5 U.S.C. 552a(b)(3)).

PURPOSE(S):

Under this matching program DOW will disclose military retirement payment and survivor benefit payment data to SSA. SSA will use the military retirement payment and survivor benefit payment data to verify information provided by applicants, recipients, deemors (*i.e.*, someone other than the eligible individual or eligible spouse whose income and resources are considered when determining an individual's eligibility for SSI and the amount of their payment), and beneficiaries of SSI payments and SVB.

CATEGORIES OF INDIVIDUALS:

The individuals whose information is involved in this matching program are SSI and SVB applicants, recipients, deemors, and beneficiaries including retired members, or their survivors, of the Uniformed Services.

CATEGORIES OF RECORDS:

SSA will provide DOW with a quarterly finder file containing approximately 10 million records of individuals for whom SSA requests data to administer the SSI and SVB programs. SSA and DOW will use Social Security numbers to conduct the match. DOW will provide a response file containing military retirement payment and survivor benefit payment data for matched records.

SYSTEM(S) OF RECORDS:

The relevant SSA system of records Systems of Records (SOR) is "Supplemental Security Income Record and Special Veterans Benefits," 60 0103. The SOR Notice (SORN) was fully published on January 11, 2006 (71 FR 1830) and updated on December 10, 2007 (72 FR 69723), July 3, 2018 (83 FR 31250–31251), November 1, 2018 (83 FR 54969), January 5, 2024 (89 FR 825), February 27, 2024 (89 FR 14554) and November 25, 2025 (90 FR 53413). The relevant DOW SOR is DMDC 01, entitled "Uniformed Services Human Resources Information System," last

published in full on March 3, 2026 (91 FR 10373).

[FR Doc. 2026–21946 Filed 10–27–26; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration**

[Docket No. FAA–2025–1193]

Notice of Order Designating U.S. Aviation Safety Team (USAST) Information as Protected From Disclosure

AGENCY: Federal Aviation Administration (FAA), Department of Transportation.

ACTION: Notice of order.

SUMMARY: This action affirms the order and responds to comments received in response to the Notice published on August 1, 2025, regarding designating U.S. Aviation Safety Team (USAST) information as protected from disclosure. The Notice proposed that safety and security information as described below be designated by an FAA Order as protected from disclosure in accordance with the provisions of the rule entitled Protection of Voluntarily Submitted Information. The designation is intended to encourage persons to voluntarily provide information to the FAA through the USAST, supporting a collaborative, data-driven strategy to reduce the risk of fatal and non-fatal aviation incidents and accidents.

DATES: October 28, 2026.

ADDRESSES: For information on where to obtain copies of documents and other information related to this action, see "How to Obtain Additional Information" in this notice.

FOR FURTHER INFORMATION CONTACT: Brian Boardman, U.S. Aviation Safety Team Secretariat, Federal Aviation Administration, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, Email: brian.boardman@faa.gov, Telephone: 771–333–1247.

SUPPLEMENTARY INFORMATION:**Background**

Under 49 U.S.C. 40123, certain voluntarily provided safety and security information is protected from disclosure to encourage persons to provide the information to the FAA. The FAA's rules for implementing 49 U.S.C. 40123 are in Title 14 of the Code of Federal Regulations (14 CFR) part 193. The FAA must first issue an order specifying why the agency finds that the information should be protected. If the FAA

Administrator issues an order designating information as protected under 49 U.S.C. 40123, that information will not be disclosed under the Freedom of Information Act (5 U.S.C. 552) or other laws except as provided in part 193, and as provided in the order designating the information as protected. This order to protect the USAST information from disclosure is issued under 14 CFR 193.11, which sets out the notice procedure for designating information as protected.

Applicability

This final order will be applicable to any FAA organization that receives safety information covered under this designation from a core member, general member, or other invited participant of the USAST, aviation community safety team, or working group chartered by the USAST. The final order will also apply to any other government agency that receives such information from the FAA. For any other government agency to receive USAST information protected from disclosure under this designation from the FAA, the agency receiving the protected information must first comply with the procedure set forth in 14 CFR 193.7(e) and this order.

A core member of the USAST is a voting organization expected to be represented at every USAST meeting (this includes but is not limited to operators, aviation industry associations, and original equipment manufacturers). A general member of the USAST is an organization that is expected to attend USAST when topics pertinent to their domain of expertise are covered (this includes, but is not limited to industry safety groups, industry labor associations, and specialized industry associations).

Description of the Safety Information To Be Protected

The FAA designates certain system-level safety issue information voluntarily provided through the USAST as protected from disclosure. These protections extend only to information covered in Section B of this document. The USAST is a collaborative leadership body representing U.S. industry and government stakeholders across the aviation community. It evolved from the legacy Commercial Aviation Safety Team (CAST) to bring together stakeholders from across aviation communities and offer a new approach and tools for addressing systemic aviation safety issues. The USAST encompasses (but is not limited to) air navigation service providers, air carriers and operators, crewmembers, aerospace

manufacturers, aerospace domain associations (*i.e.*, labor unions, standards bodies, etc.), and aviation community safety teams.

Aviation community safety teams are government-industry partnerships that work to improve aviation safety by collectively analyzing aviation safety data to identify emerging issues and develop strategies to address and prioritize safety issues. Participation in an aviation community safety team is entirely voluntary. These teams rely on the voluntary submission of proprietary industry safety data to develop informed mitigations/communications appropriate to their communities. Aviation community safety teams develop voluntary safety enhancements as intervention strategies to prevent or mitigate risk in the NAS. Existing aviation community safety teams include the Commercial Aviation Safety Team (CAST), General Aviation Joint Safety Committee (GAJSC), U.S. Helicopter Safety Team (USHST), Drone Safety Team (DST), and their working groups.

The USAST is led by two executive-level chairpersons: one selected from the aviation industry and one from the U.S. Government (an FAA employee selected by the FAA Administrator). The FAA also participates in the USAST with multiple FAA lines of business as core members. This designation applies only to non-FAA members of the USAST, aviation community safety teams, and workgroups chartered by the USAST. As such, this designation should not be construed as an opportunity for the FAA to protect data it obtains non-voluntarily and provides to the USAST. The core function of the USAST is to improve aviation safety through voluntary participation in safety analysis to address potential systemic safety issues.

A system-level safety issue is anything that involves a potential hazard that affects one or more segments of the aviation industry or affects multiple entities within a single segment of the industry. As part of the system-level safety issue lifecycle, the USAST relies on voluntary identification and submission of safety issues from the aviation industry and aviation community safety teams. Prior to a system-level safety issue arising to the USAST it is generally worked through an appropriate aviation community safety team to ensure that the issue is systemic and has all the necessary supporting information and data. The USAST may also conduct safety promotion activities with the aviation industry to communicate safety issues and/or safety enhancements to

the appropriate aviation community safety team for awareness.

Non-FAA USAST members aviation community safety teams and workgroups chartered by the USAST, submit voluntarily provided aviation safety issues to the USAST. Safety issues submitted to the USAST are considered "FAA-received" at the moment of submission because of the FAA's role as USAST co-chair.. The information the FAA receives from the USAST comes in through different formats. These formats may include USAST meeting agendas, meeting minutes, presentations, reports, and analyses. The information provided in these documents is voluntarily provided to the USAST and FAA release of this information would jeopardize industry participation and reduce the willingness of the aviation industry to submit voluntary safety data to the USAST.

USAST risk management processes fully rely on confidence that voluntarily submitted safety and security information is protected from disclosure. Protection of voluntarily provided system-level safety issue information allows the USAST to appropriately assess the information without the potential negative effects from involuntary release of the information. The voluntary contributions from aviation stakeholders to the USAST are core components to the success of these teams and programs. Without certain protections for USAST information, reports, data, and work products could not be protected by the U.S. Government, which would prevent the FAA from working with the aviation industry to develop proactive voluntary safety enhancements to mitigate systemic risk in the NAS.

Summary of the Protected Safety Information

A. Who may participate?

Entities eligible for participation include non-FAA core members, general members, and other invited participants of the USAST. These entities include air navigation service providers, air carriers and operators, crewmembers, aerospace industry manufacturers, aviation community safety teams, and aerospace industry associations or organizations (*i.e.*, labor unions, standards bodies, etc.).

B. What voluntarily provided information will be protected from disclosure?

1. All voluntarily provided information documented in meeting agendas, briefings, or minutes before, at,

or after any USAST meeting or event that covers systemic aviation safety and security issues, emerging threats, changing risks, or accident precursors.

2. All voluntarily provided safety or security issue information submitted to and coordinated within the USAST. This includes but is not limited to the title of the issue, description, submitter information, supporting data provided by any non-government entity, and user feedback surrounding the issue.

3. All information, reports, data, and work products conducted through the USAST chartered workgroups or aviation community safety teams related to the preliminary analysis of voluntarily provided safety or security issues. This also includes routine monitoring of voluntarily provided aviation safety data for known risks, emerging risks, and anomalies.

4. All information, reports, data, and work products from the safety risk assessment processes conducted by the USAST related to safety issues voluntarily submitted to the USAST. For a safety issue, this includes the identification of hazards, analysis of risk, assessment of risk, development of risk controls, safety enhancements, and related documentation of the safety risk and risk management processes.

5. All information related to identifying if a USAST participant has implemented a safety enhancement recommended by USAST that is reported to the FAA.

6. All information related to the level of safety enhancement implementation, and the results of implementation provided to the USAST that is reported to the FAA.

7. Reports, agendas, minutes, and other documents prepared by the USAST, aviation community safety team, or workgroup established by the USAST that is based on information related to the implementation of voluntary safety enhancements.

8. Any information voluntarily provided related to the implementation of safety enhancements and/or the effectiveness of these safety enhancements in mitigating underlying risks.

C. How can persons participate?

Eligible entities that comprise the USAST participate by voluntarily providing aviation system-level safety or security issue data to the USAST or its respective aviation community safety teams as part of the normal operating processes or on an ad-hoc basis.

D. What is the duration of this protection?

Information provided to the USAST as part of its ongoing processes in support of the identification of systemic safety issues and implementation of safety enhancements will be protected indefinitely.

Summary of Findings

The FAA designates voluntary information received from the USAST related to potential system-level safety issues and safety enhancements as protected under 49 U.S.C. 40123 and 14 CFR 193.7 based on the following findings:

1. Summary of why FAA finds that the information will be provided voluntarily.

The core principle of the USAST is voluntary participation. USAST participants, who take part in the safety analysis, determine the feasibility of safety enhancements, and agree to implement the enhancements do so voluntarily. Contributions of safety issue information to the USAST are voluntarily provided by the aviation industry with the collective understanding that the information will not be disclosed and that it will be used to collectively improve aviation safety by all USAST's participants. The FAA receives the voluntarily provided aviation safety issues from the USAST.

2. Description of the type of information that may be voluntarily provided under the program and why the FAA finds that the information is safety or security related.

USAST participants voluntarily provide safety or security related information that identifies possible system-level safety issues in the NAS. A system-level safety or security issue is anything that involves a potential hazard that affects one or more segments of the aviation industry or affects multiple entities within a single segment of the industry. As part of the USAST's system-level safety issue lifecycle, the USAST relies on identification and voluntary submission of safety issues from the industry. USAST participants also voluntarily provide information about safety enhancements implementation, the method of implementation, the process to evaluate the implementation, and any other information, such as best practices related to the implementation of safety enhancements. The FAA finds that the information is safety or security related because it contributes towards achieving and measuring USAST aviation safety goals (e.g., reducing the risk of fatal and non-fatal accidents.) by using voluntary,

proactive, data-driven strategies to get results and develop collaborative safety interventions.

3. Summary of why the FAA finds that the disclosure of the information would inhibit persons from voluntarily providing that type of information.

USAST processes fully rely on confidence that voluntarily submitted safety and security information from any of the USAST chartered stakeholders, attendees, or representatives is protected from disclosure. The protection provided by this designation will encourage these participants to voluntarily report potential safety issues without fear of uncontrolled and involuntary public release of this information. Eligible entities part of the USAST will be reluctant to share sensitive safety information with the FAA if it might be subject to disclosure.

Additionally, release of the voluntarily provided information to the public may be incomplete, unreliable, or sensitive. The release of this information may adversely affect the USAST participants and the aviation industry, discouraging further voluntary information sharing. Protecting system-level safety issue information voluntarily provided through the USAST allows the FAA and USAST to appropriately assess the information and work with the aviation industry to create safety interventions.

Participation in the USAST is not required by regulation. The U.S. aviation industry also has wide discretion on how they leverage the voluntary safety enhancements to address the identified safety risk as the recommended enhancements are not required by regulation. Any disclosure of information listed above would have an adverse effect on aviation safety.

4. Summary of why receiving the information aids in fulfilling the FAA's safety and security responsibilities.

The FAA finds that receipt of safety issue information through the USAST aids in fulfilling the FAA's safety responsibilities because it provides early identification of potential hazards in the NAS, allowing the FAA to proactively address risk in the system. This offers the FAA a unique opportunity to work with the aviation industry to avoid incidents or accidents. The USAST can provide safety-related information that may not be available to the FAA from any other source and can help to improve the FAA's ability to modify procedures, policies, and regulations to improve aviation safety. The FAA and U.S. Department of Transportation (DOT) safety goals, as highlighted in the DOT's Strategic Plan

FY2026–2030, include “supporting voluntary government and industry information sharing”. With the information provided to the FAA through the USAST, the FAA and industry will be able to identify systemic aviation safety issues, emerging threats, changing risks, and accident precursors effectively and proactively and determine whether safety enhancements to address these issues are effective. This information supports the FAA's safety goals for proactive identification of systemic safety or security issues in the NAS.

5. Summary of why withholding the information from disclosure is consistent with FAA safety responsibilities and when withholding the information from disclosure would not be consistent with FAA safety responsibilities as described in 14 CFR 193.9.

Withholding such information from disclosure is consistent with the FAA's safety responsibilities because without voluntary contributions of safety or security issues from the aviation industry and information on the implementation of the safety enhancements, the FAA will not be able to proactively manage safety in the NAS.

Unless the FAA can provide assurance that USAST safety information will not be disclosed, the FAA may not receive information that would otherwise be used to improve aviation safety. Without this information, the FAA will be limited in their ability to understand the possible system-level safety issues that the aviation industry may be experiencing and take proactive steps to address those issues before any accidents or incidents occur in the NAS. Withholding the information from disclosure encourages entities to voluntarily provide it because they know it is protected once the FAA receives it.

Withholding the information from disclosure would not be consistent with FAA safety responsibilities as described in 14 CFR 193.9 when reports or other data involve possible criminal activity, substance abuse, improper use of controlled substances and/or alcohol, intentional falsification, reckless conduct (i.e., an act (or failure to act) demonstrating a gross disregard for, or deliberate indifference to, safety or a safety standard), intentional conduct (i.e., an act (or failure to act) while knowing that such conduct is contrary to a regulation or statute, or is otherwise prohibited), or generally demonstrate a lack of care, judgment, or responsibility. The protection described in this

proposed designation will not apply to information falling into these instances.

The FAA may disclose de-identified information, as set forth in part 193, to explain the need for changes in FAA policies and regulations. The FAA may (in consultation with the USAST) release information as set forth in part 193 to communicate its work with aviation safety communities or other third parties involved with the USAST to address system-level safety issues. In either of these situations, the FAA may release de-identified, aggregate, and summarized information (in consultation with the USAST) derived from information reported about the implementation of safety enhancements, or safety issue information provided through the USAST.

The FAA may provide USAST information to other government agencies only if each agency meets the requirements in 14 CFR 193.7(e). The FAA may provide USAST information to third parties only if the third party provides adequate assurance in writing that it has a safety or security need for the information, it will protect the information from further release, and it will limit access to those with a need to know to carry out safety responsibilities.

6. Summary of how the FAA will distinguish information protected under Part 193 from information the FAA receives from other sources.

Information received by the FAA from the USAST will be clearly labeled as follows to be protected under this designation:

WARNING: This information may be protected from disclosure under 49 U.S. Code (U.S.C.) Section 40123 and 14 Code of Federal Regulations (CFR) Part 193.

In this way, the information protected under this order will be easily identified and distinguished from information the FAA receives from other sources.

How To Obtain Additional Information

You will find the FAA's order supporting this notice in the Dynamic Regulatory System, accessed via drs.faa.gov.

Final Designation

The FAA hereby designates the information submitted to the USAST as described in this designation to be protected under 49 U.S.C. 40123 and 14 CFR part 193.

Issued in Washington, DC, on October 14, 2026.

Matthew Cabak,

Acting Executive Director, Office of Safety Risk Management (ASR-1).

[FR Doc. 2026-21964 Filed 10-27-26; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA-2026-9076]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: National Air Tours Safety Standards

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on August 4, 2026. Once anonymous comment was received stating: "The agency completely omit the estimated number of annual respondents or total annual responses, making it impossible for the public to verify how the 2,560-hour total burden was calculated." The collection involves requirements in FAA regulations that set safety and oversight rules for a broad variety of sightseeing and commercial air tour flights to improve the overall safety of commercial air tours by requiring all air tours to submit information.

DATES: Written comments should be submitted by November 27, 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: Sandra Ray by email at: Sandra.ray@faa.gov; phone: 412-546-7344.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120-0717.

Title: National Air Tours Safety

Standards.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on August 4, 2026 (91 FR 49482). FAA regulations set safety and oversight rules for a broad variety of sightseeing and commercial air tour flights to improve the overall safety of commercial air tours by requiring all air tour operators to submit information. The FAA uses the information it collects and reviews to ensure compliance and adherence to regulations and, if necessary, take enforcement action on violators of the regulations.

Respondents: Commercial Air Tour Operators (Total Responses 12,834).

Frequency: Most Requirements are annual, One requirement is one time only.

Estimated Average Burden per Response: Burden varies per individual requirement. Average burden is 5 hours per response.

Estimated Total Annual Burden: 2,560 Hours.

Issued in Washington, DC, on October 23, 2026.

Sandra L. Ray,

Aviation Safety Inspector, AFS-260.

[FR Doc. 2026-21927 Filed 10-27-26; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2020-0191]

Parts and Accessories Necessary for Safe Operation; Application for Exemption Renewal From Loomis Armored US, LLC

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition; grant of application for renewal of exemption.

SUMMARY: FMCSA announces its decision to grant an exemption renewal to Loomis Armored US, LLC (USDOT 252201) (Loomis) to allow the company to continue operating armored vehicles with welded-shut cab doors and the addition of two doors behind the cab. FMCSA has analyzed the exemption renewal application and the public comments and determined that the exemption, subject to the terms and

conditions set forth below, is likely to achieve a level of safety that is equivalent to, or greater than the level that would be achieved absent such exemption.

DATES: The exemption is effective October 14, 2026 and expires October 13, 2031.

FOR FURTHER INFORMATION CONTACT: Mr. Jose Moreno, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, FMCSA; by email at MCPSV@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to <https://www.regulations.gov/docket/FMCSA-2020-0191/document> and choose the document to review. To view comments, click this notice, then click "Document Comments." If you do not have access to the internet, you may view the docket online 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

Current Regulatory Requirements

Section 393.203(a) of the FMCSRs requires that (1) cab compartment doors or door parts used as an entrance or exit shall not be missing or broken; (2) doors shall not sag so that they cannot be properly opened or closed; and (3) no door shall be wired shut or otherwise secured in the closed position so that it cannot be readily opened. Section 393.203(a) includes an exception when the vehicle is loaded with pipe or bar stock that blocks the door and the cab has a roof exit.

Applicant's Request

On October 18, 2021, FMCSA granted Loomis a 5-year exemption to allow the company to operate armored vehicles with welded-shut cab doors and the addition of two doors behind the cab. Loomis's application for renewal of exemption was described in detail in a **Federal Register** notice published on April 2, 2026 (91 FR 16808) and will not be repeated as the facts have not changed.

IV. Public Comments

The Agency received 2 comments, one supporting and one opposing renewal of the exemption.

Apex Transportation, Inc. commented, "This exemption should be renewed."

AWM Associates stated that FMCSA should deny the exemption because Loomis did not clarify that the vehicles in question are involved in interstate commerce and therefore subject to the FMCSRs. AWM Associates questioned whether the vehicles meet the glazing requirements in 49 CFR 393.60 and noted the vehicles may not meet applicable State requirements. AWM Associates suggested that FMCSA explicitly state that the exemption only applies to vehicles engaged in interstate commerce and does not apply to vehicles operating in intrastate commerce. Finally, AWM attached a summary of vehicle violations of 49 CFR parts 393 and 396 from Loomis's inspection history.

V. FMCSA Decision

FMCSA has evaluated Loomis's application and the comments received. The Agency believes that granting the exemption renewal to allow Loomis to weld shut the cab doors and add two new doors behind the cab is likely to achieve a level of safety that is equivalent to, or greater than, the level of safety that would be achieved absent such exemption.

In response to the comment from AWM Associates, Loomis is registered with FMCSA as an interstate motor carrier and stated in its initial application that it operates nationwide, which is sufficient to establish the interstate nature of its operations. FMCSA notes that its exemption decisions include preemption language stating that "States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce." FMCSA reviewed the violation data attached to AWM's comment and determined that none of the violations related to the exemption. In addition, AWM's questions about whether Loomis's vehicles meet glazing and other State requirements are outside the scope of the exemption application.

By welding the original driver and passenger cab doors and relocating the entry point to the vehicle through two high-security biometric enabled doors behind the cab and an emergency escape hatch, Loomis has reduced the possibility of unauthorized persons entering the vehicle. Loomis personnel are trained in the use of armored vehicle systems, including the use of the new doors and their operation in the event of a rollover. The new doors are also equipped with an override system in case of a loss of power which can only be accessed by personnel from the inside.

Since granting the original 5-year exemption in October 2021, FMCSA has not become aware of any safety concerns involving the armored vehicles operating under the exemption.

VI. Exemption

A. Applicability of Exemption

The Agency hereby grants the exemption from 49 CFR 393.203(a) for a renewed 5-year period, beginning October 14, 2026 and ending October 13, 2031. During the exemption period, Loomis armored vehicles may weld shut the original equipment manufacturer doors given the addition of the emergency escape hatch to the rear of the driver's seat, and the messenger exterior door to the rear of the front passenger's seat. Specifically, the exemption allows Loomis to weld shut the cab doors and install two new high security doors behind the cab.

B. Terms and Conditions

1. This exemption is limited to commercial motor vehicles operated by Loomis and does not apply to any other operators of armored vehicles.

2. Loomis may weld shut the cab doors and add two new doors behind the cab of its armored vehicles. No

further vehicle modifications are covered under this exemption.

3. Loomis must comply with all other applicable Federal Motor Carrier Safety Regulations (49 CFR parts 350–399).

C. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

VII. Termination

The exemption will be revoked if: (1) Loomis fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of Title 49, chapter 313 or section 31136.

Derek D. Barrs,
Administrator.

[FR Doc. 2026–21950 Filed 10–27–26; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Transfer of Federally Assisted Property

AGENCY: Federal Transit Administration (FTA), United States Department of Transportation (USDOT).

ACTION: Notice of Intent (NOI) to Transfer Federally Assisted Land or Facility.

SUMMARY: The Federal Transit Administration (FTA) issues this notice to advise Federal agencies that New Jersey TRANSIT (NJ TRANSIT) intends to transfer a 2.17-acre portion of a 9.27-acre parcel to the Jersey City Municipal Utilities Authority (JCMUA).

DATES: Any Federal agency interested in acquiring the Subject Property must notify the FTA Region II Office of its interest no later than November 27, 2026.

ADDRESSES: Interested parties should notify FTA Region II by writing to Michael Culotta, Regional Administrator, Federal Transit Administration, One Bowling Green, Room 428 New York, NY 10004.

FOR FURTHER INFORMATION CONTACT:

Michael Culotta, Regional Administrator, Federal Transit Administration, One Bowling Green, Room 428, New York, NY 10004, or at (212) 668–2170.

SUPPLEMENTARY INFORMATION: New Jersey TRANSIT (NJ TRANSIT) intends to transfer a 2.17-acre portion of a 9.27-acre parcel (the 2.17-acre portion is referred to herein as the Subject Property) to the Jersey City Municipal Utilities Authority (JCMUA). NJ TRANSIT has not used the Subject Property since the mid-1990s and it has remained vacant. NJ TRANSIT has determined it no longer needs the Subject Property for public transportation purposes, and requests FTA approval to transfer it to the JCMUA if no Federal agency is interested in acquiring the Subject Property for Federal use. JCMUA will utilize the Subject Property for its proposed stormwater pump station, which will assist in alleviating flooding in parts of Jersey City, NJ.

Background

Federal public transportation law (49 U.S.C. 5334(h)) sets forth requirements for the transfer of capital assets. Specifically, if a recipient of FTA assistance decides an asset acquired with assistance under 49 U.S.C. Chapter 53 is no longer needed for the purpose for which it was acquired, FTA may authorize the recipient to transfer the asset to a local governmental authority to be used for a public purpose with no further obligation to the Government. 49 U.S.C. 5334(h)(1)(A).

Determinations

FTA may authorize a transfer for a public purpose other than mass transportation only if FTA determines:

(i) The asset will remain in public use for at least five (5) years after the date the asset is transferred;

(ii) There is no purpose eligible for assistance under Chapter 53 of title 49, United States Code, for which the asset should be used;

(iii) The overall benefit of allowing the transfer is greater than the interest of the Government in liquidation and return of the financial interest of the Government in the asset, after considering fair market value and other factors; and

(iv) Through an appropriate screening or survey process, that there is no interest in acquiring the asset for Government use if the asset is a facility or land.

FTA has determined the above requirements (i), (ii), and (iii) have been met.

Federal Interest in Acquiring Land or Facility

This Notice implements the requirements of 49 U.S.C. 5334(h)(1)(A)(iv). Accordingly, FTA hereby provides notice of the availability of the Subject Property further described below. Any Federal agency interested in acquiring the Subject Property should promptly notify the FTA. If no Federal agency is interested in acquiring the Subject Property, FTA will transfer the property.

Additional Description of Land

The Subject Property is a 2.17 acre unimproved parcel located at 510 Pacific Avenue, Jersey City, in the County of Hudson, New Jersey, Block 15801, Part of Lots 2 & 65.

Authority: 49 U.S.C. 5334(h), 49 CFR 1.91.

Michael Culotta,

Regional Administrator, Region II.

[FR Doc. 2026–21945 Filed 10–27–26; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2026–2344]

Denial of Motor Vehicle Defect Petition, DP26–004

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

ACTION: Notice of denial of a petition for a defect investigation.

SUMMARY: This notice sets forth the reasons for the denial of a defect petition, DP26–004, submitted by Mr. Richard De Leon (the Petitioner) to NHTSA (the Agency) by letter received December 22, 2025. The petition requests that the Agency initiate a safety defect investigation into the hydraulic control unit (HCU) for the Anti-lock Braking System (ABS) on the Model Year (MY) 2010 Ford Fusion Hybrid. The petition alleges that an illuminated ABS malfunction indicator lamp (MIL) is associated with a failure of the ABS HCU, resulting in ABS malfunction, loss of traction and electronic stability control functions, and reduced braking performance on slippery road surfaces.

After conducting a technical review of the petition and other information, the Agency concluded that the issues raised by the petition do not warrant a new defect investigation. Accordingly, the Agency denied the petition.

FOR FURTHER INFORMATION CONTACT:

David Engel, Vehicle Defect Division C, Office of Defects Investigation, NHTSA, 1200 New Jersey Avenue SE, Washington, DC 20590. Telephone: 202-650-3796. Email: david.engel@dot.gov.

SUPPLEMENTARY INFORMATION:**Introduction**

Interested persons may petition NHTSA requesting that the Agency initiate an investigation to determine whether a motor vehicle or an item of replacement equipment does not comply with an applicable motor vehicle safety standard or contains a defect that relates to motor vehicle safety. 49 U.S.C. 30162(a)(2); 49 CFR 552.1. Upon receipt of a properly filed petition, the Agency conducts a technical review of the petition, material submitted with the petition, and any additional information. 49 U.S.C. 30162(a)(2); 49 CFR 552.6. The technical review may consist solely of a review of information already in the possession of the Agency, or it may include the collection of information from a motor vehicle manufacturer and other sources. After conducting the technical review and considering appropriate factors, which may include, but are not limited to, the nature of the complaint, allocation of Agency resources, Agency priorities, the likelihood of uncovering sufficient evidence to establish the existence of a defect and the likelihood of success in any necessary enforcement litigation, the Agency will grant or deny the petition. See 49 U.S.C. 30162(a)(2); 49 CFR 552.8.

Background Information

The Office of Defects Investigation (ODI) received a petition on December 22, 2025, requesting a defect investigation into the hydraulic control unit (HCU) for the Anti-lock Braking System (ABS) on the MY 2010 Ford Fusion Hybrid.

Summary of Petition

The petition alleges that an illuminated ABS MIL is associated with a failure of the ABS HCU, resulting in ABS malfunction, loss of traction and electronic stability control functions, and reduced braking performance, particularly on slippery road surfaces.

Office of Defects Investigation Analysis

ODI conducted an analysis of complaints submitted to ODI for the subject vehicle population along with data submitted by Ford. The Petitioner alleged that the condition in the subject vehicles was comparable to the defect

addressed by NHTSA recall No. 19V904, which covered certain MY 2006–2010 Ford Fusion, Mercury Milan, and Lincoln MKZ vehicles. The population of this recall consisted of the non-hybrid variants of these models. The recall addressed a defect where the ABS valves in the HCU could remain stuck open due to a chemical reaction with aged DOT 3 brake fluid, potentially causing extended brake pedal travel and increasing the risk of a crash.¹ No visual or audible warning was presented to the driver in this scenario.

The MY 2010 Ford Fusion Hybrid is equipped with a different brake apply system in which the traditional hydraulic (friction) brakes are blended with the hybrid regenerative brake system. In this system, the brake master cylinder is electrically activated and provides force feedback through the brake pedal to the driver. Unlike the recalled models, Petitioner's 2010 Ford Fusion Hybrid would not experience the same defect, as a stuck-open normally closed valve within its ABS HCU does not result in increased brake pedal travel. This condition is further supported by the relative complaint rates in the two populations: ODI found the complaint rate of the recalled MY 2010 Fusion vehicles was six times higher than that of the subject MY 2010 Fusion Hybrid vehicles, which supports a significant difference in the design and performance of the brake system and components.

As the Petitioner stated, most of the subject hybrid vehicle VOQs cited an illuminated ABS MIL. The vehicles in 19V904 did not present the driver with an illuminated MIL or associated diagnostic trouble code (DTC). Since the MY 2010 Ford Fusion Hybrid presented with a brake MIL, the failure mode differs from that of the non-hybrid population, which did not trigger an illuminated warning light. Additionally, given the age of the subject vehicles (MY 2010), the low complaint volume is consistent with expected wear and tear rather than an actionable safety defect trend.

Due to the age of the vehicles and the lack of an actionable safety defect trend—stemming from differences in the ABS HCU between non-hybrid MY 2010 Ford Fusions and Petitioner's hybrid MY 2010 Ford Fusion—ODI is denying this Defect Petition as it has not found an unreasonable risk to highway safety. The Agency reserves the right to take additional action if warranted by future circumstances. To review the reports

¹ DOT 3 brake fluid is a conventional, glycol-ether-based hydraulic fluid used to transfer force from the brake pedal to a vehicle's brakes.

cited in the Closing Resume ODI Report Identification Number document, go to [NHTSA.gov](https://www.nhtsa.gov).

Authority: 49 U.S.C. 30162(d) and 49 CFR Part 552; delegation of authority at 49 CFR 1.95(a).²

Eileen Sullivan,

Associate Administrator for Enforcement.

[FR Doc. 2026-21957 Filed 10-27-26; 8:45 am]

BILLING CODE 4910-59-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 and vessels 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. The vessels placed on the SDN List have been identified as property in which a blocked person has an interest.

DATES: This action was issued on July 14, 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 July 14, 2026, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons and vessels are blocked under the relevant sanctions authorities listed below.

² The authority to determine whether to approve or deny defect petitions under 49 U.S.C. & 30162(d) and 49 CFR part 552 has been further delegated to the Associate Administrator for Enforcement.

Individuals

1. RAHBAR MADANI, Mohammad Reza, Iran; DOB 10 Jun 1973; POB Tehran, Iran; nationality Iran; alt. nationality Dominica; Gender Male; Passport RA020092 (Dominica) expires 29 Apr 2032; National ID No. 0057373078 (Iran) (individual) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of Executive Order 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 materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

2. KAALUND, Martin Austin (a.k.a. KAALUND, Martin), Singapore; Dubai, United Arab Emirates; DOB 11 Apr 1973; POB Copenhagen, Denmark; nationality Denmark; Gender Male (individual) [IRAN-EO13902] (Linked To: HOUSE OF SHIPPING INVESTMENT FZCO).

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, HOUSE OF SHIPPING INVESTMENT FZCO, a person whose property and interests in property are blocked pursuant to E.O. 13902.

3. RAKHBARMADANI, Ali (Arabic: علي راخبارماداني) (a.k.a. RAHBARMADANI, Ali), Dubai, United Arab Emirates; Russia; DOB 28 Jan 1975; POB Tehran, Iran; nationality Iran; alt. nationality Russia; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport 516737186 (Russia); alt. Passport B97499327 (Iran) expires 29 Feb 2028 (individual) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

4. RONCO, Alessandra, United Arab Emirates; DOB 1980 to 1981; POB Italy; nationality Italy; Gender Female (individual) [IRAN-EO13902] (Linked To: EVORIT STRATEGY CONSULTING LLC-FZ).

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, EVORIT STRATEGY CONSULTING LLC-FZ, a person whose property and interests in property are blocked pursuant to E.O. 13902.

5. DEHKORDI, Asghar Aghili, United Arab Emirates; DOB 21 Feb 1976; POB Shahrekord, Iran; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 4621568566 (Iran)

(individual) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

6. GEORGE, Jijin, United Arab Emirates; DOB 16 Jan 1994; POB Trivandrum, India; nationality India; Gender Male (individual) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

7. MOGHADAS, Behzad (Arabic: بهزاد مقدس), United Arab Emirates; Iran; DOB 27 Jul 1987; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

8. TSERNOSJOV, Maksim, United Arab Emirates; DOB 23 Aug 1985; nationality United Kingdom; Gender Male; Passport 124013929 (United Kingdom) (individual) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

9. VISHAVDEEP, Gautam, United Arab Emirates; DOB 27 Jul 1967; POB Ludhiana, India; nationality India; Gender Male; Passport Z5557980 (India) (individual) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

10. ZAHED, Hossein Ghorbani (a.k.a. GHORBANIZAHED, Hossein), Dubai, United Arab Emirates; DOB 13 Oct 1982; POB Tehran, Iran; nationality Iran; alt. nationality Dominica; Gender Male; National ID No. 0075194953 (Iran) (individual) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.</PHOTO>

Entities

1. AVA TARABAR DARYA COMPANY (Arabic: شرکت آوا ترابر دریا) (a.k.a. AVA TARABAR DARYA CO LTD), No. 0 Ground Floor, Imam Khomeini Boulevard, Nezami Alley, Post Neighborhood, Khorramshahr, Khuzestan 6415953185, Iran; Organization Established Date 07 Jun 2022; National ID No. 14011215616 (Iran); Identification Number IMO 6327561; Business Registration Number 3920 (Iran) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

2. SEPEHR NOOR MOBIN COMPANY (Arabic: شرکت سپهر نور مبین) (a.k.a. SEPEHR NOOR MOBIN SHIPPING CO), Unit 3, Level 2, Mellat Tower, Ansari Street, Vali-e Asr Avenue, Tehran 1967713374, Iran; Unit 201, 2nd Floor, No. 42, Enghelab Street, 12th Farvardin Street, corner of Nowruz Alley, Tehran 1314694161, Iran; Organization Established Date 20 Dec 2015; National ID No. 14005480093 (Iran); Identification Number IMO 5920175; Registration Number 484305 (Iran) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

3. SEA LEAD SHIPPING AGENCY INDIA PRIVATE LIMITED, C-1102, Godrej Coliseum Near Somaiya Hospital Road, Lokmanya Pan Bazar, Sion (East) Sion, Mumbai 400022, India; Organization Established Date 20 Sep 2022; C.I.N. U63030MH2022FTC390753 (India) [IRAN-EO13902] (Linked To: SEA LEAD SHIPPING PTE. LTD.).

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, SEA LEAD SHIPPING PTE. LTD, a person whose property and interests in property are blocked pursuant to E.O. 13902.

4. SEA LEAD SHIPPING DMCC (Arabic: سي ليد شيبينغ م.د.م.س), Unit No 3057, Level 1, Jewellery & Gemplex 3, DMCC Business Centre, New Dubai, Dubai, United Arab Emirates; Organization Established Date 29 Jul 2018; License DMCC-506318 (United Arab Emirates); Business Registration Number DMCC130391 (United Arab Emirates); Economic Register Number (CBLS) 11469509 (United Arab Emirates) [IRAN-EO13902] (Linked To: SEA LEAD SHIPPING PTE. LTD.).

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, SEA LEAD SHIPPING PTE. LTD, a person whose property and interests in property are blocked pursuant to E.O. 13902.

5. SEA LEAD SHIPPING MARSHALL ISLANDS LTD, Trust Company Complex, Ajeltake Road, Ajeltake Island, Majuro 96960, Marshall Islands; Organization Established Date 07 Dec 2021; Identification Number IMO 6275841; Residency Number 112141 (Marshall Islands) [IRAN-EO13902] (Linked To: SEA LEAD SHIPPING PTE. LTD.).

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, SEA LEAD SHIPPING PTE. LTD, a person whose property and interests in property are blocked pursuant to E.O. 13902.

6. SEA LEAD SHIPPING PTE. LTD., 78 Shenton Way, #10 Unit No. 001, Singapore 79120, Singapore; Organization Established Date 28 Mar 2017; Identification Number IMO 6104579; Registration Number 201708559N (Singapore) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

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, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

7. VOLTA SHIPPING SERVICES LLC (Arabic: فولتا لخدمات الشحن ذ م م) (a.k.a. VOLTA SHIPPING SERVICES FZCO), Office No 1-024, Al Garhoud, Deira, Dubai, United Arab Emirates; Business Cluster Building 3 108, Fl 1, Dubai, United Arab Emirates; Organization Established Date 07 Jun 2017; alt. Organization Established Date 01 Oct 2023; License 784220 (United Arab Emirates); alt. License 50335 (United Arab Emirates); Chamber of Commerce Number 290374 (United Arab Emirates); Registration Number 1290166 (United Arab Emirates); Economic Register Number (CBLS) 10957213 [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for,

or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

8. WE FREIGHT SHIPPING LLC (Arabic: **وي فرايت للشحن ذ م م**) (a.k.a. WE FREIGHT INVESTMENT FZCO (Arabic: **وي فرايت انفيستمنت ش م ح**); a.k.a. WE FREIGHT SHIPPING AND LOGISTICS THAILAND LIMITED; a.k.a. WEFREIGHT INDIA PRIVATE LIMITED), Office No B2007-160, Trade Centre First, Bur Dubai, Dubai, United Arab Emirates; BCB3 218, Second Floor, Business Cluster Building 3, Dubai CommerCity, Dubai, United Arab Emirates; Unit 711, CTS-266, 266/1-172, Prakashwadi Sale, Village Gundavali, A.K. Road, Chakala Midc, Mumbai, Maharashtra 400093, India; 4th, A/409, Ratnakar 9 Square, Mansi Circle Road, Vastrapur, Ahmedabad, Gujarat 380015, India; 71 Sukhumvit Road, Soi Sukhumvit 101/1, Phra Khanong 10260, Thailand; Website <https://wefreight.com/>; Organization Established Date 15 Feb 2016; alt. Organization Established Date 18 Jul 2019; alt. Organization Established Date 2022; alt. Organization Established Date 28 Jun 2022; License 752407 (United Arab Emirates); alt. License 18363 (United Arab Emirates); Chamber of Commerce Number 264431 (United Arab Emirates); Registration Number 2238929 (United Arab Emirates); alt. Registration Number U74999MH2019PTC328229 (India); alt. Registration Number 0105565143097 (Thailand); Economic Register Number (CBLS) 10936447 (United Arab Emirates); alt. Economic Register Number (CBLS) 11905125 (United Arab Emirates) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

9. AARE LINES INC., Trust Company Complex, Ajeltake Road, Majuro, Ajeltake Island 96960, Marshall Islands; Organization Established Date 17 May 2022; Identification Number IMO 6324125 [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

10. LUBECK SHIPPING LLC (Arabic: **لوبيك للشحن ذ م م**), Office No 1-032, Al Garhoud, Deira, Dubai, United Arab Emirates; BCB3 119, First Floor, Business Cluster - Building 3, Dubai CommerCity, Dubai, United Arab Emirates; Organization Established Date 31 May 2018; Identification Number IMO 6418449; License 808300 (United Arab Emirates); Chamber of Commerce Number 305098 (United Arab Emirates); Economic

Register Number (CBLS) 11306758 (United Arab Emirates) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

11. GLAVOS SHIPPING FZCO (Arabic: غلافوس شيبينج ش م ح), Dubai, United Arab Emirates; Organization Established Date 05 Aug 2024; License 50426 (United Arab Emirates) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

12. SAI WAN SHIPPING LIMITED (Chinese Traditional: 西環船務有限公司), 21/F CMA Building, 64 Connaught Road, Hong Kong, China; Organization Established Date 06 Jul 2018; Business Registration Number 69604477 (Hong Kong) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

13. AL KINA COMMERCIAL BROKER LLC (Arabic: الكينا للوساطة التجارية ش ذ م م), 1909 and 1901 Burj Khalifa, Burj Dubai, Dubai, United Arab Emirates; Organization Established Date 26 Feb 2019; License 827606 (United Arab Emirates); Chamber of Commerce Number 316979 (United Arab Emirates); Registration Number 1395777 (United Arab Emirates); Economic Register Number (CBLS) 11500101 (United Arab Emirates) [IRAN-EO13902] (Linked To: RAKHBARMADANI, Ali).

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, ALI RAKHBARMADANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

14. DEZERA SHIPPING FZCO (Arabic: ديزيرا شيبينج ش م ح), First Floor, Building A2, BCA2 125 Business Cluster, Dubai CommerCity, Dubai, United Arab Emirates; Organization Established Date 08 Jul 2024; License 50420 (United Arab Emirates) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

15. EVORIT STRATEGY CONSULTING LLC-FZ

(Arabic: ايفوريت ستراتيغي كونسالتينج ذ م م-منطقة حرة), 6th Floor, The Meydan Hotel Grandstand, Meydan Road, Nad Al Shiba, Bur Dubai, Dubai, United Arab Emirates; M Floor, Business Center 1, Nad Al Shiba, Bur Dubai, Dubai, United Arab Emirates; Website <https://cvoritglobal.com>; Organization Established Date 24 Sep 2025; License 2537797.01 (United Arab Emirates) [IRAN-EO13902] (Linked To: KAALUND, Martin Austin).

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, MARTIN AUSTIN KAALUND, a person whose property and interests in property are blocked pursuant to E.O. 13902.

16. BSG MANAGEMENT LTD (Arabic: بي اس جي مانجمنت لميتد), Unit L28-05, Level 28, Dubai International Financial Centre, Bur Dubai, Dubai, United Arab Emirates; Organization Established Date 19 Aug 2021; License 4945 (United Arab Emirates); Economic Register Number (CBLS) 11723352 (United Arab Emirates) [IRAN-EO13902] (Linked To: ZAHED, Hossein Ghorbani).

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, HOSSEIN GHORBANI ZAHED, a person whose property and interests in property are blocked pursuant to E.O. 13902.

17. GOLDEN NEST GROUP LTD, Boulevard Plaza Tower, 2, Office 2504, Dubai, United Arab Emirates; Ellen L Skelton Building, 2nd Floor, Fishers Lane, Road Town, Tortola VG1110, Virgin Islands, British; Organization Established Date 07 Mar 2023; Company Number OE028423 (United Kingdom); Registration Number 2103334 (Virgin Islands, British) [IRAN-EO13902] (Linked To: ZAHED, Hossein Ghorbani).

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, HOSSEIN GHORBANI ZAHED, a person whose property and interests in property are blocked pursuant to E.O. 13902.

18. HANSA SHIPPING INC., Trust Company Complex, Ajeltake Road, Majuro, Ajeltake Island, Marshall Islands; Organization Established Date 03 May 2024; Identification Number IMO 0171833; Entity Code 125737 (Marshall Islands) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

19. HOPE 1 SHIPPING INC, Trust Company Complex, Ajeltake Road, Ajeltake Island, Majuro 96960, Marshall Islands; Organization Established Date 04 Feb 2022; Identification Number IMO 6335884; Entity Code 112970 (Marshall Islands) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

20. NUVETRRO SHIPPING INC, Building 1, Nelson Spring Business Complex, Nelson Spring, Nevis, Saint Kitts and Nevis; Organization Established Date 2025; Identification Number IMO 0422802 [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

21. OCEAN SEARUM ONE LIMITED, Level 54, Hopewell Centre, 183, Queen's Road East, Wan Chai, Hong Kong, China; Organization Established Date 23 May 2022; Identification Number IMO 6335306; Business Registration Number 74066533 (Hong Kong) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

22. PLATINUM KNIGHTS LTD, Trust Company Complex, Ajeltake Road, Ajeltake Island, Majuro 96960, Marshall Islands; Organization Established Date 04 Jan 2024; Identification Number IMO 6505796; Entity Code 123580 (Marshall Islands) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

23. VELTRRIVO SHIPPING INC, Building 1, Nelson Spring Business Complex, Nelson Spring, Nevis, Saint Kitts and Nevis; Organization Established Date 2025; Identification Number IMO 0422793 [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

24. KANGRI 1 INC, Trust Company Complex, Ajeltake Road, Ajeltake Island, Majuro 96960, Marshall Islands; Organization Established Date 06 Dec 2024; Identification Number IMO 0134656; Registration Number 129141 (Marshall Islands) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Designated pursuant to section 1(a)(iii) of E.O. 13902 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902.

Vessels

1. ARKANOOR 2 (EPDO3) General Cargo Iran flag; Vessel Year of Build 1989; Vessel Registration Identification IMO 8727848; MMSI 422075700 (vessel) [IRAN-EO13902] (Linked To: SEPEHR NOOR MOBIN COMPANY).

Identified as property in which SEPEHR NOOR MOBIN COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

2. ARKANOOR 3 (EPDP9) General Cargo Iran flag; Vessel Year of Build 1990; Vessel Registration Identification IMO 8832083; MMSI 422077300 (vessel) [IRAN-EO13902] (Linked To: SEPEHR NOOR MOBIN COMPANY).

Identified as property in which SEPEHR NOOR MOBIN COMPANY, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

3. ERIKA (EPCL7) General Cargo Iran flag; Vessel Year of Build 1987; Vessel Registration Identification IMO 8721454; MMSI 422049900 (vessel) [IRAN-EO13902] (Linked To: RAHBAR MADANI, Mohammad Reza).

Identified as property in which MOHAMMAD REZA RAHBAR MADANI, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

4. SEA ANCHOR General Cargo Unknown flag; Former Vessel Flag Palau; Vessel Year of Build 1984; Vessel Registration Identification IMO 8858099

(vessel) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Identified as property in which MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

5. SEA CASTLE General Cargo Unknown flag; Former Vessel Flag Palau; Vessel Year of Build 1983; Vessel Registration Identification IMO 8891572 (vessel) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Identified as property in which MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

6. SEA CRUISER General Cargo Unknown flag; Former Vessel Flag Palau; Vessel Year of Build 1989; Vessel Registration Identification IMO 8729963 (vessel) [IRAN-EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Identified as property in which MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

7. SEPEHR PAYAM (EPCU9) Container Ship Iran flag; Vessel Year of Build 1995; Vessel Registration Identification IMO 9110535; MMSI 422058200 (vessel) [IRAN-EO13902] (Linked To: AVA TARABAR DARYA COMPANY).

Identified as property in which AVA TARABAR DARYA COMPANY, a

person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

8. GEMMA (T8A3035) General Cargo Palau flag; Vessel Year of Build 2011; Vessel Registration Identification IMO 9509097; MMSI 511873000 (vessel) [IRAN-EO13902] (Linked To: LUBECK SHIPPING LLC).

Identified as property in which LUBECK SHIPPING LLC, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

9. NADIA (V4CL4) Container Ship St Kitts & Nevis flag; Vessel Year of Build 1997; Vessel Registration Identification IMO 9122461; MMSI 341765000 (vessel) [IRAN-EO13902] (Linked To: AARE LINES INC.).

Identified as property in which AARE LINES INC., a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

10. PAYA LEBAR (V2C2003) Container Ship Antigua & Barbuda flag; Vessel Year of Build 1997; Vessel Registration Identification IMO 9134232; MMSI 305003400 (vessel) [IRAN-EO13902] (Linked To: SEA LEAD SHIPPING PTE. LTD.).

Identified as property in which SEA LEAD SHIPPING PTE. LTD., a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

11. SEA GALLEON General Cargo Unknown flag; Former Vessel Flag

Palau; Vessel Year of Build 1990; Vessel Registration Identification IMO 8843666 (vessel) [IRAN–EO13902] (Linked To: SHAMKHANI, Mohammad Hossein).

Identified as property in which MOHAMMAD HOSSEIN SHAMKHANI, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

12. DARIKA (3E8661) Chemical/Oil Tanker Panama flag; Vessel Year of Build 2011; Vessel Registration Identification IMO 9506693; MMSI 352005381 (vessel) [IRAN–EO13902] (Linked To: HANSA SHIPPING INC.).

Identified as property in which HANSA SHIPPING INC., a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

13. ELPINIKI (a.k.a. “CORN”) (8PQT) General Cargo Barbados flag; Vessel Year of Build 2014; Vessel Registration Identification IMO 9606015; MMSI 314159000 (vessel) [IRAN–EO13902] (Linked To: OCEAN SEARUM ONE LIMITED).

Identified as property in which OCEAN SEARUM ONE LIMITED, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

14. HOPE 1 (V2C2008) Bulk Carrier Antigua and Barbuda flag; Vessel Year of Build 2012; Vessel Registration Identification IMO 9514339; MMSI 305008400 (vessel) [IRAN–EO13902] (Linked To: HOPE 1 SHIPPING INC).

Identified as property in which HOPE 1 SHIPPING INC, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

15. JADE (V2C2005) General Cargo Antigua and Barbuda flag; Vessel Year of Build 2010; Vessel Registration Identification IMO 9418999; MMSI 305005400 (vessel) [IRAN–EO13902] (Linked To: NUVETRRO SHIPPING INC).

Identified as property in which NUVETRRO SHIPPING INC, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

16. OPAL (V2C2006) General Cargo Antigua and Barbuda flag; Vessel Year of Build 2012; Vessel Registration Identification IMO 9467158; MMSI 305006400 (vessel) [IRAN–EO13902] (Linked To: VELTRRIVO SHIPPING INC).

Identified as property in which VELTRRIVO SHIPPING INC, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

17. VIRENT (3E3834) Chemical/Oil Tanker Panama flag; Vessel Year of

Build 2007; Vessel Registration Identification IMO 9332171; MMSI 352002167 (vessel) [IRAN–EO13902] (Linked To: PLATINUM KNIGHTS LTD).

Identified as property in which PLATINUM KNIGHTS LTD, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

18. CICCIO (V2C2007) Container Ship Antigua & Barbuda flag; Vessel Year of Build 2000; Vessel Registration Identification IMO 9192442; MMSI 305007400 (vessel) [IRAN–EO13902] (Linked To: KANGRI 1 INC).

Identified as property in which KANGRI 1 INC, a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

19. SHENTON WAY (3E8302) Container Ship Panama flag; Vessel Year of Build 1998; Vessel Registration Identification IMO 9146314; MMSI 352005129 (vessel) [IRAN–EO13902] (Linked To: SEA LEAD SHIPPING PTE. LTD.).

Identified as property in which SEA LEAD SHIPPING PTE. LTD., a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

20. TANJONG PAGAR 1 (3E8523) Container Ship Panama flag; Vessel Year of Build 2007; Vessel Registration Identification IMO 9404508; MMSI 352006054 (vessel) [IRAN–EO13902] (Linked To: SEA LEAD SHIPPING PTE. LTD.).

Identified as property in which SEA LEAD SHIPPING PTE. LTD., a person whose property and interests in property are blocked pursuant to E.O. 13902, has an interest.

(Authority: E.O. 13902.)

Lisa M. Palluconi,

Deputy Director, Office of Foreign Assets Control.

[FR Doc. 2026–21944 Filed 10–27–26; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Internal Revenue Service Advisory Council; Public Meeting

AGENCY: Internal Revenue Service, Department of Treasury.

ACTION: Notice of public meeting.

SUMMARY: The Internal Revenue Service Advisory Council will hold a public meeting.

DATES: Wednesday, November 18, 2026.

ADDRESSES: 1111 Constitution Ave. NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT:

Anna Millikan, Office of National Public Liaison, at 202–317–6564 or send an email to PublicLiaison@irs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, the Internal Revenue Service announces the Internal Revenue Service Advisory Council (IRSAC) will hold a public meeting on Wednesday, November 18, 2026, from 11:30 a.m. to 3:00 p.m. Eastern Time.

The meeting will be held in person at 1111 Constitution Ave. NW, Washington, DC. Members of the public planning to attend should register by November 13 by contacting Anna Millikan at 202–317–6564 or sending an email to PublicLiaison@irs.gov.

Issues to be discussed may include, but are not limited to: *IRS Resources Enabling Increased Revenue Collection; Reducing Compliance Friction; Ghost Preparers; Tax-Related Identity Theft Resolution: Transparency, Timing, and Resource Dedication; Elective Withholding by Partnerships for Partners; Simplification of Form W–4 and Changes to Protect Employee Privacy; Processing of Penalty and Interest Abatement Requests; Use of Artificial Intelligence by Tax Return Preparers; Professional Responsibility, Confidentiality, and the Use of Taxpayer Information; Worker Classification and Form SS–8, Determination of Worker Status for Purposes of Federal Employment Taxes and Income Tax Withholding; Small Business Tax Literacy: Focus on Individuals with Business Income; Electronic Filing and Processing of Form 8802: Application for US Residency Certification and Digitalization of Form 6166: Certification of US Tax Residency; Form 1099–DIV: Dividends and Distributions Improvements for US Federal Government Obligations for Regulated Investment Companies; Tax Treatment of Prediction Markets Business Activities and Associated Gains & Losses; Rationalization and Modernization of the Form W–2G Regime; Large Corporations Access to Electronic Transcripts; TIN Match Expansion; Elective Form 1099 Reporting in Lieu of Schedule K–1 Reporting; Corporate Taxpayer Identity Protection Framework; Modernizing Administration of Certain Passive Foreign Investment Companies (PFICs); Collection: Improve Early Identification of Non-Filed Employment Tax Returns and Collection of Unpaid Employment Taxes; Artificial Intelligence Use for Tax Exempt and Governmental Entities;*

Broaden the IRS Interpretation of "Essential Government Function" Under Section 7871 of the Internal Revenue Code; Promoting the Use of IRS Digital Communications; 410(b) Coverage Testing Grace Period; Extending Tax Status Regulations for Wholly-Owned Tribal Business Entities to Partially-Owned Tribal Business Entities; Suspension of Beard Returns; Strengthening the Analytical Basis for Addressing Earned Income Tax Credit Returns that Report Large Schedule C Losses; OBBBA Refundable Adoption Tax Credit Education and Outreach Strategy; Unapplied Payments—Secondary SSN; Engaging and Encouraging Saver's Match Participation; Preventing Tax Scams and Fraud Suffered by Low-to-Moderate Income Taxpayers by Enhancing and Expanding the Successful VITA Program; Improving Business CAF Functionality to Reduce Authorization Burden and Expand Digital Representation; and Math Error Notice Drafts, Format and Clarity—Initial Reactions. The meeting agenda will be posted online prior to the meeting at the IRSAC web page, www.irs.gov/irsac.

Should you wish the IRSAC to consider a written statement germane to the Council's work, file the statement by sending an email to PublicLiaison@irs.gov by November 13, 2026.

Dated: October 26, 2026.

Margaret A. Romaniello,
Designated Federal Officer, IRSAC, Office of National Public Liaison, Internal Revenue Service.

[FR Doc. 2026-21966 Filed 10-27-26; 8:45 am]

BILLING CODE 4831-GV-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on Certain Transfers of Domestic Stock or Securities by U.S. Persons to Foreign Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before December 28, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue

Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include "OMB Control No. 1545-1478" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this collection should be directed to Kerry Dennis, (202) 317-5751.

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: Certain Transfers of Domestic Stock or Securities by U.S. Persons to Foreign Corporations.

OMB Control Number: 1545-1478.

Regulation Number: T.D. 8702.

Abstract: This regulation relates to certain transfers of stock or securities of domestic corporations to foreign corporations pursuant to the corporate organization, reorganization, or liquidation provisions of the Internal Revenue Code. Under section 367(a), these transfers generally result in the recognition of gain unless an applicable exception is satisfied. To qualify for the exception provided under 26 CFR 1.367(a)-3(c), the U.S. target company must comply with applicable reporting requirements and certain other conditions. The information collected is

used by the IRS to determine whether the requirements for the exception have been satisfied.

Current Actions: There is no change to the previously approved information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 100.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 1,000.

Dated: October 21, 2026.

Kerry Dennis,
Tax Analyst.

[FR Doc. 2026-21921 Filed 10-27-26; 8:45 am]

BILLING CODE 4831-GV-P

DEPARTMENT OF THE TREASURY

Proposed Collection; Comment Request

AGENCY: Departmental Offices; Department of the Treasury.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to comment on renewal of a currently approved information collection that is to be proposed for approval by the Office of Management and Budget. The Office of International Affairs within the Department of the Treasury is soliciting comments concerning Treasury International Capital (TIC) Forms BC, BL-1, BL-2, BQ-1, BQ-2, and BQ-3 (called the "TIC B forms"). The collections are mandatory.

DATES: Written comments should be received on or before December 28, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments to Kurt Schuler, International Portfolio Investment Data Systems, Department of the Treasury, Room 1050, 1500 Pennsylvania Avenue, NW, Washington DC 20220. In view of possible delays in mail delivery, please also notify Mr. Schuler by email (comments2TIC@treasury.gov) or telephone (202-622-7527).

FOR FURTHER INFORMATION CONTACT:

Copies of the proposed forms and instructions are available on the Treasury's TIC Forms web page, <https://home.treasury.gov/data/treasury-international-capital-tic-system/tic-forms-instructions>. Requests for additional information should be directed to Mr. Schuler

(comments2TIC@treasury.gov or 202–622–7527).

SUPPLEMENTARY INFORMATION:

Titles: Treasury International Capital (TIC) Form BC, “Monthly Report of U.S. Dollar Claims of Financial Institutions on Foreign Residents”; TIC BL–1, “Monthly Report of U.S. Dollar Liabilities of Financial Institutions to Foreign Residents”; TIC BL–2, “Monthly Report of Customers’ U.S. Dollar Liabilities to Foreign Residents”; TIC BQ–1, “Quarterly Report of Customers’ U.S. Dollar Claims on Foreign Residents”; TIC BQ–2, Part 1, “Quarterly Report of Foreign Currency Liabilities and Claims of Financial Institutions and of their Domestic Customers’ Foreign Currency Claims with Foreign Residents”; TIC BQ–2, Part 2, “Report of Customers’ Foreign Currency Liabilities to Foreign Residents”; and TIC BQ–3, “Quarterly Report of Maturities of Selected Liabilities and Claims of Financial Institutions with Foreign Residents.”

OMB Control Number: 1505–0016.

Abstract: Forms BC, BL–1, BL–2, BQ–1, BQ–2, BQ–3 are part of the Treasury International Capital (TIC) reporting system, which is required by law (22 U.S.C. 286f; 22 U.S.C. 3103; E.O. 10033; 31 CFR 128) and are designed to collect timely information on international portfolio capital movements. Reporting organizations report data as follows: own monthly claims on foreign residents, denominated in U.S. dollars (Form BC); own monthly liabilities to foreign residents, denominated in U.S. dollars (BL–1); U.S. customers’ monthly liabilities to foreign residents, denominated in U.S. dollars (BL–2); U.S.-resident customers’ quarterly U.S. dollar claims on foreign residents, denominated in foreign currencies (BQ–1); own and their domestic customers’ quarterly claims and liabilities with foreign residents, denominated in foreign currencies (BQ–2); remaining maturities of all their own quarterly U.S. dollar and foreign currency liabilities and claims (excluding securities) with foreign residents. This information is used by the U.S. Government in the formulation of international financial and monetary policies and for the preparation of the U.S. balance of payments accounts and the U.S. international investment position.

Current Actions: The following changes are proposed to the Instructions for the Treasury International Capital (TIC) Form B Reports. (1) Raise the reporting thresholds for the TIC BC, BL–1, BL–2, BQ–1, BQ–2 reports from \$50 million for the Grand Total row and \$25 million for any individual line item to

\$250 million for the Grand Total row and \$100 million for any individual line item (“Exemption Levels,” section I.C.4). (2) Expand allowable signatures to include an individual performing equivalent functions to a duly authorized officer (“Signature Requirements,” section I.F.3). (3) Clarify that reporters include Central Clearing Counterparties (“Who Must Report,” section I.C). (4) Clarify that the definition of Foreign Official Institutions for the purposes of TIC reporting excludes enterprises that are owned by a government but that do not serve a governmental function such as national defense (“Foreign Official Institutions,” sections II.B.1a, III.B.1a, and IV.B.1a) (5) Clarify wording about how to fill in columns of TIC Form BQ–3 (“Non-Negotiable Deposits & Brokerage Balances (Column 1),” section VIII.C.1.a, and “Loan Claims Excluding Resale Agreements (Column 3),” section VIII.C.1.c).

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Forms: BC, BL–1, BL–2, BQ–1, BQ–2, and BQ–3.

Estimated Number of Respondents: BC, 235; BL–1, 283; BL–2, 80; BQ–1, 46; BQ–2, 148; BQ–3, 118.

Estimated Average Time per Respondent per Filing: BC, 11.6 hours; BL–1, 7.9 hours; BL–2, 9.2 hours; BQ–1, 4.3 hours; BQ–2, 8.1 hours; and BQ–3, 10.5 hours. The average time varies, and is estimated to be generally twice as many hours for major data reporters as for other reporters.

Estimated Total Annual Burden Hours: BC, 32,712 hours for 12 reports per year; BL–1, 26,794 hours for 12 reports per year; BL–2, 8,842 hours for 12 reports per year; BQ–1, 795 hours for 4 reports per year; BQ–2, 4,801 hours for 4 reports per year; and BQ–3, 4,956 hours for 4 reports per year.

Request for Comments: Comments submitted in response to this notice will be summarized and/or 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 written comments concerning: (a) whether Forms BC, BL–1, BL–2, BQ–1, BQ–2, and BQ–3 are necessary for the proper performance of the functions of the Office, including whether the information will have practical uses; (b) the accuracy of the above estimate of the burdens; (c) ways to enhance the quality, usefulness and clarity of the information to be collected; (d) ways to minimize the reporting and/or record keeping burdens on respondents,

including the use of information technologies to automate the collection of the data; and (e) estimates of capital or start-up costs of operation, maintenance and purchase of services to provide information.

Kurt Schuler,

Administrator, International Portfolio Investment Data Reporting Systems.

[FR Doc. 2026–21924 Filed 10–27–26; 8:45 am]

BILLING CODE 4810-AK-P

UNIFIED CARRIER REGISTRATION PLAN

Sunshine Act Meetings

TIME AND DATE: October 28, 2026, 12:00 p.m. to 3:00 p.m., Eastern Time.

PLACE: The meeting will also be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll), Meeting ID: 922 9451 2618, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is <https://kellen.zoom.us/join/92294512618>.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the “Board”) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

Proposed Agenda

I. Welcome and Call To Order—UCR Board Chair

The UCR Board Chair will welcome attendees, call the meeting to order, call roll for the Board, confirm the presence of a quorum, and facilitate self-introductions.

II. Verification of Publication of Meeting Notice—UCR Executive Director

The UCR Executive Director will verify publication of the meeting notice on the UCR website and distribution to the UCR contact list via email, followed by subsequent publication of the notice in the **Federal Register**.

III. Review and Approval of Board Agenda—UCR Board Chair

For Discussion and Possible Board Action

The proposed Agenda will be reviewed. The Board will consider action to adopt.

Ground Rules

- Board actions taken only in designated areas on the agenda

IV. Approval of Minutes of the July 29, 2026, UCR Board Meeting—UCR Board Chair

For Discussion and Possible Board Action

Draft Minutes from the July 29, 2026, UCR Board meeting will be reviewed. The Board will consider action to approve.

V. Report of FMCSA—FMCSA Representative

The Federal Motor Carrier Safety Administrator (FMCSA) Deputy Administrator or representative will provide a report on any relevant agency activity.

VI. Amendments to the UCR Agreement—UCR Governance Task Force Chair, UCR Chief Legal Officer and UCR Executive Director

For Discussion and Possible Board Action

The UCR Governance Task Force Chair, UCR Chief Legal Officer and UCR Executive Director will present and explain to the Board proposed amendments to the UCR Agreement recommended by the Governance Task Force. The Board may take action to initiate the process to amend the UCR Agreement pursuant to the UCR Agreement Amendment Policy, including the establishment of an Amendments Subcommittee to review the recommendations of the Governance Task Force and make additional recommendations.

VII. Subcommittee Reports

Audit Subcommittee—UCR Audit Subcommittee Chair

The UCR Audit Subcommittee Chair will present a current state Compliance Summary Report to the Board.

Dispute Resolution Subcommittee—UCR Dispute Resolution Subcommittee Chair

No report.

Education and Training Subcommittee—UCR Education and Training Subcommittee Chair

The UCR Education and Training Subcommittee Chair will provide an update on key projects and initiatives, including the ongoing development of the learning management program and training efforts for various stakeholders.

Enforcement Subcommittee—UCR Enforcement Subcommittee Chair and Vice-Chair

The UCR Enforcement Subcommittee Chair and Vice-Chair will provide an update on current and planned initiatives, including efforts to enhance UCR enforcement efficiency, and recognition of states and inspectors.

Finance Subcommittee—UCR Finance Subcommittee Chair and UCR Depository Manager

A. 2027 and 2028 Registration Fee Update—UCR Finance Subcommittee Chair and UCR Executive Director

The UCR Finance Subcommittee Chair and UCR Executive Director will provide an update on the 2027 and 2028 Registration Year fee recommendation.

B. Revenues From 2025 and 2026 Registration Fees—UCR Depository Manager

The UCR Depository Manager will review the revenues received from the 2025 and 2026 plan year registration fees.

C. 2025 External Financial Audit Update—UCR Finance Subcommittee Chair and UCR Depository Manager

The UCR Finance Subcommittee Chair and UCR Depository Manager will provide an update on the UCR Plan's 2025 External Financial Audit.

D. Request For Proposals (RFP) Process for the 2026 Audit—UCR Finance Subcommittee Chair and UCR Depository Manager

For Discussion and Possible Board Action

The UCR Finance Subcommittee Chair and UCR Depository Manager will discuss an RFP for the 2026 UCR audit. The Finance Subcommittee, at its October 15, 2026, meeting passed a motion to recommend that the UCR Plan Board authorize the issuance of an RFP to obtain an independent financial audit of the UCR Plan Depository for the fiscal year ending December 31, 2026. The purpose of the RFP is to solicit competitive proposals from qualified independent certified public accounting firms to ensure an objective, professional and cost-effective audit. The Board may take action to authorize the issuance of an RFP for the 2026 independent financial statement audit of the UCR Plan Depository and further, to authorize the Finance Subcommittee to oversee the proposed RFP evaluation process and recommend to the Board an auditor to be selected.

E. Management Report—UCR Finance Subcommittee Chair and UCR Depository Manager

The UCR Finance Subcommittee Chair and UCR Depository Manager will provide an update on UCR finances and related topics.

Industry Advisory Subcommittee—UCR Industry Advisory Subcommittee Chair

No report.

Governance Task Force—UCR Governance Task Force Chair

The UCR Governance Task Force Chair will provide an update on topics to include the UCR agreement, subcommittee charters and other related governance topics.

VIII. Contractor Reports—UCR Board Chair

UCR Executive Director Update

The UCR Executive Director will provide a report covering his recent activity on behalf of the UCR Plan.

UCR Administrator Update (Kellen)

No substantive updates from the UCR Chief of Staff beyond the Management, Depository, Operations and Communication reports provided.

DSL Transportation Services, Inc.

DSL Transportation Services, Inc. will report on the latest data from the FARs program, Tier 5 and 6 unregistered motor carriers and other matters.

Seikosoft

Seikosoft will provide an update on its recent/new activity related to the UCR's National Registration System.

IX. Other Business—UCR Board Chair

The UCR Board Chair will call for any other business, old or new, from the floor.

X. Adjournment—UCR Board Chair

The UCR Board Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern daylight time, October 21, 2026, at: <https://plan.ucr.gov>.

CONTACT PERSON FOR MORE INFORMATION:

Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305-3783, eleaman@board.ucr.gov.

Alex B. Leath,

Chief Legal Officer, Unified Carrier Registration Plan.

[FR Doc. 2026-21956 Filed 10-26-26; 11:15 am]

BILLING CODE 4910-YL-P

**DEPARTMENT OF VETERANS
AFFAIRS****[OMB Control No. 2900–0161]****Agency Information Collection Activity
Under OMB Review: Medical Expense
Report****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 27, 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. 2900–0161.”

FOR FURTHER INFORMATION CONTACT:

VA PRA information: Dorothy Glasgow, 202–461–1084, VAPRA@va.gov.

SUPPLEMENTARY INFORMATION:

Title: 21P–8416, Medical Expense Report.

OMB Control Number: 2900–0161.
<https://www.reginfo.gov/public/do/PRASearch>.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 21P–8416 allows claimants and beneficiaries to report unreimbursed medical expenses to reduce their countable income for needs-based benefit programs, such as VA Pension and Parents’ Dependency and Indemnity Compensation (DIC). These expenses are deducted from otherwise countable income to determine eligibility for income-based

benefits and the rate payable. Veteran Service Representatives use the information on the form to adjust benefits.

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 91 FR 48230, July 30, 2026.

Affected Public: Individuals or Households.

Estimated Annual Burden: 30,000 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 60,000.

(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. 2026–21982 Filed 10–27–26; 8:45 am]

BILLING CODE 8320–01–P



FEDERAL REGISTER

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Part II

Department of Health and Human Services

45 CFR Parts 170 and 172

Health Data, Technology, and Interoperability: ONC Deregulatory Actions
To Unleash Prosperity; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary****45 CFR Parts 170 and 172**

RIN 0955-AA09

Health Data, Technology, and Interoperability: ONC Deregulatory Actions To Unleash Prosperity

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule focuses on deregulatory actions identified in HHS regulations regarding health information technology standards, implementation specifications, and certification criteria and regarding certification programs for health information technology. This final rule reduces burden, offers flexibility to both developers and providers, and supports innovation through the removal and revision of certain certification criteria and regulatory provisions.

DATES: This final rule is effective on December 28, 2026, except for amendatory instructions 7, 10, and 12 which are effective January 1, 2027. The incorporation by reference of certain material listed in the rule was approved by the Director of the Federal Register between February 12, 2010, and October 1, 2025.

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Programs and Implementation, Office of the National Coordinator for Health Information Technology, 202-690-7151.

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b. Patient Health Information Capture	Since the inception of the ONC Health IT Certification Program (Certification Program) (42 U.S.C. 300jj–11(c)(5)), ONC has aimed to implement and administer the Certification Program in the least burdensome manner that supports an administration's policy goals. Throughout the years, we have worked to improve the Certification Program with a focus on ways to reduce burden, offer flexibility to both developers and providers, and support innovation. Over the past 15 years, we have established a set of regulatory requirements that have provided a foundation for our voluntary Certification Program. As we look to the future, we reviewed the existing requirements and made updates. Through both formal notice and comment rulemaking and informal engagements, we received suggestions on how to update the Certification Program to meet current market needs. This final rule includes deregulatory actions that: take into consideration suggestions and comments received on the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity Proposed Rule (90 FR 60970) ("Proposed Rule"); account for the current and future state of technology; reduce burden on health IT developers; and promote innovation for health IT developers, providers, and other interested parties.
6. Public Health Certification Criteria	These efforts directly align with Administration goals as outlined in E.O. 14192 (Unleashing Prosperity through
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Deregulation)¹ and E.O. 14267 (Reducing Anti-Competitive Regulatory Barriers).² By removing burdensome and unnecessary requirements of the Certification Program, this final rule supports providers in caring for their patients. Developers of certified health IT will have more time to support providers' specific technological needs. Further, by increasing competition in the certified health IT market that will come from reduced barriers to entry for the certification of health IT, providers also will have more choices to meet their health IT needs.

America's interoperability arc in healthcare has bent decisively toward Fast Healthcare Interoperability Resources (FHIR®)-based application programming interfaces (APIs). An open, interoperable health data ecosystem invites entrepreneurship, drives innovation, and cements American leadership and competitiveness in the expanding digital health marketplace. As discussed in this deregulatory final rule, we aggressively reduce and remove long-standing functionality-oriented and non-FHIR-based certification criteria from the Certification Program. While this approach will directly and rapidly reduce compliance burdens for health IT developers that participate in the Certification Program, more broadly, it will enable ONC to reset the Certification Program's regulatory scope and establish a new foundation on which to build FHIR-based API requirements in the future. This will allow more creative super intelligence³ (SI)-enabled interoperability solutions that combine FHIR with newer standards to emerge, such as Model Context Protocol (MCP), which "standardizes how applications provide context to Large Language Models (LLMs),"⁴ and will further embrace the 21st Century Cures Act (Pub. L. 114–255) (Cures Act)'s reference to successor technology and standards in the API Condition of Certification.⁵

While FHIR provides the potential for better, faster, and more consistent ways to address emerging market needs and policy imperatives, more work is needed for certain use cases. We intend to continue to fully engage industry and

our Federal partners, such as CMS, to rapidly advance FHIR specifications for regulatory readiness. We also intend to sharpen the Certification Program's future focus to prioritize FHIR-based APIs that, consistent with all legal requirements: (1) enhance automation and API performance; (2) move beyond read-only interactions; and (3) expand the scope of data available to support clinical efficiency, patient-centered care, and use cases focused on timely reporting (e.g., public health, quality, government programs).

The transition to a FHIR-based API ecosystem is a strategic imperative and an investment in the US's interoperability future. Successful execution of this vision will require a collective commitment from clinicians, patients, payers, policymakers, and software developers, alike. Together, we can build interoperable solutions that meet today's challenges and anticipate tomorrow's opportunities.

In this final rule, we have finalized the removal or revision of certain certification criteria that are consistent with our drive toward and our support for the FHIR standard. The push toward universal adoption of FHIR is not just important for secure, streamlined data access, it is a critical step toward modernizing our healthcare system with the ultimate goal of Making America Healthy Again.

B. Summary of Major Provisions

For the purposes of this final rule, we have reviewed and responded to comments on a narrowed set of proposals from the Proposed Rule. Comments received in response to other Proposed Rule proposals not discussed in this final rule remain under review and consideration. The Proposed Rule proposals not discussed in this final rule may, in the future, be included in subsequent final rules or as revised proposals in subsequent proposed rules.

1. Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology (Part 170)

a. Certification Criteria for Health Information Technology

In the Proposed Rule, we identified certification criteria for proposed removal or revision (90 FR 60973). We noted that the removal or revision of the identified certification criteria would reduce burden and costs for health IT developers and clinicians by eliminating the need to design and meet specific certification functionalities; to prepare, test, and certify health IT in

certain instances; and to maintain conformance to certification requirements. As explained in the Proposed Rule, we have observed that over time certification is likely no longer a primary factor driving improvements or compliance in particular areas. Throughout this final rule, we include finalized revisions and removals of certification criteria that we believe are no longer necessary to advance interoperability and no longer provide a strong market driver for initial adoption and implementation of the certified functionalities.

In the Proposed Rule, out of the 60 certification criteria that are currently in effect, we proposed to remove 34 and revise seven. In this final rule, we have finalized the removal of 14 certification criteria and the revision of seven criteria. Of the revised criteria, one of the more substantial revisions reduces the scope of the "decision support interventions" certification criterion to fully remove the super intelligence "model card" requirements in § 170.315(b)(11)(iv) for source attribute support and § 170.315(b)(11)(v) for source attribute access and modification. We have retained and made no changes to 39 certification criteria, which include new and revised criteria that were adopted in the Health Data, Technology, and Interoperability: Electronic Prior Authorization and Real-Time Prescription Benefit (HTI-4) final rule (90 FR 37130). The HTI-4 final rule was a "rider" in the FY 2026 CMS Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System final rule (90 FR 36536). The new and revised criteria that were finalized in the HTI-4 final rule were: three new electronic prior authorization API criteria, a new "real-time prescription benefit" criterion,⁶ a revised e-prescribing criterion, and two criteria supporting modular API capabilities.

b. Standards and Implementation Specifications for Health Information Technology

As proposed in the Proposed Rule (90 FR 60973), in some instances where we finalize the removal or revision of a certain certification criterion, we also finalize the removal of the standard(s) that is referenced by the certification criterion. In some cases, we have finalized the removal of standards consistent with a certification criterion transition period until January 1, 2027.

⁶ ONC finalized the real-time prescription benefit criterion in order to implement section 119(b)(3) of Title I of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).

¹ <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>.

² <https://www.federalregister.gov/documents/2025/04/15/2025-06463/reducing-anti-competitive-regulatory-barriers>.

³ Executive Order 14434 (September 29, 2026); <https://www.federalregister.gov/documents/2026/10/02/2026-20321/inaugurating-the-era-of-super-intelligence>.

⁴ <https://modelcontextprotocol.io/introduction>.

⁵ 42 U.S.C. 300jj–11(c)(5)(D)(iv).

In one circumstance, we retain a standard that was referenced in a certification criterion that we removed for purposes of health IT interoperability alignment.⁷ We also finalized the removal of standards that are outdated and no longer referenced in the Certification Program.

c. Terms and Definitions

We have finalized, as proposed, to make conforming edits to the terms and definitions in § 170.102. We revised the definition of “Base EHR” to remove references to certification criteria that we have removed from the Code of Federal Regulations (CFR). We have also removed the term (and associated definition) “Common Clinical Data Set” because this is no longer referenced in part 170.

d. Conditions and Maintenance of Certification Requirements for Health IT Developers

We have finalized our proposals to make conforming edits for several Conditions and Maintenance of Certification requirements, including the “Assurances” (§ 170.402), “Application Programming Interfaces” (§ 170.404), and “Attestations” (§ 170.406) Conditions and Maintenance of Certification requirements (90 FR 61001 through 61003).

In addition to conforming edits, we also finalized our proposal to descope the “Real World Testing” Condition and Maintenance of Certification requirements (§ 170.405) with deregulatory actions related to real world testing plans, results, and the use of the standards version advancement process (SVAP). As noted in the Proposed Rule, these actions are consistent with the enforcement discretion notice we issued on June 30, 2025.⁸ Lastly, we finalized most, but not all, of our proposals to remove and descope measures associated with the “Insights” Condition and Maintenance of Certification requirements (§ 170.407).

e. ONC Health IT Certification Program Administrative Requirements

We have finalized our proposals to make conforming edits, to remove references to certification criteria that

we proposed to remove in the Proposed Rule, in subpart E of 45 CFR part 170, (specifically, in §§ 170.523, 170.550, 170.555, and 170.570 (90 FR 60973)). We have also finalized a revision to § 170.523 to remove references to the Assistant Secretary for Technology Policy (ASTP).

2. Trusted Exchange Framework and Common Agreement (Part 172)—Restoring the Office of the National Coordinator (ONC)

We have finalized the removal of all references to ASTP within 45 CFR part 172.

C. Severability

It is our intent that each provision of this final rule be severable from other provisions of this final rule. This means that if any provision of this final rule is held to be invalid or unenforceable facially, or as applied to any person or plaintiff, or stayed pending further judicial or agency action, we intend that such provision shall be severable from other provisions of this final rule, and from rules and regulations currently in effect. We provided notice of this intent in the HTI–5 Proposed Rule (90 FR 60974). It is also our intent that, unless such provision shall be held to be utterly invalid or unenforceable, it be construed to give the provision maximum effect permitted by law including in the application of the provision to other persons not similarly situated or to other, dissimilar circumstances from those where the provision may be held to be invalid or unenforceable.

In this final rule, we have finalized provisions that are intended to and will operate independently of each other, even if multiple of them serve the same or similar general purpose(s) or policy goal(s). Where a provision is necessarily dependent on another, the context generally makes that clear (such as by cross-reference to a particular standard, requirement, condition, or pre-requisite). Where a provision that is dependent on one that is stayed or held invalid or unenforceable (as described in the preceding paragraph) is included in a subparagraph, paragraph, or section within part 170 of 45 CFR, our intention is that other provisions of such subparagraph(s), paragraph(s), or section(s) operate independently of said provision and would remain in effect.

If any revision to any provision of part 170 (such as a revision to a certification criterion in part 170) were stayed or held to be invalid or unenforceable as applied to any person, plaintiff, or circumstance, we explained our intent that such provision—and any section or

paragraph of part 170 that may reference such provision—be construed to give the provision maximum effect permitted by law including in the application of the provision to other persons not similarly situated or to other, dissimilar circumstances from those where the provision may be held to be invalid or unenforceable.

D. Costs and Benefits

The Regulatory Impact Analysis (RIA) includes an updated analysis of the costs and benefits associated with the finalized proposals in this final rule. The finalized deregulatory actions provide substantial relief for developers of certified health IT and significant cost savings realized from the revision and removal of certain Certification Program requirements. The cost savings have been estimated using the best available data and modeled on the costs estimated and finalized in prior ONC rulemakings. The finalized deregulatory actions reduce the effort for developers of certified health IT to meet ongoing Certification Program requirements and reduce entry barriers for new Certification Program participants. The finalized actions, importantly, return resources back to developers of certified health IT to innovate with their technology, improve interoperability and third-party integration, and focus on the needs of their customers. We do not expect costs to be associated with these finalized deregulatory actions. We expect the finalized deregulatory actions to result in significant benefits for health IT developers, providers, ONC-Authorized Certification Bodies (ONC-ACBs), ONC-Authorized Testing Laboratories (ONC-ATLs), and ONC. Generally, these benefits are in the form of cost and time savings and reductions in administrative burden to comply with Certification Program requirements. The finalized actions reduce the scope and breadth of Certification Program requirements.

The analysis included in this final rule indicates that the finalized updates to the Certification Program would result in \$0 in implementation and compliance costs on developers of certified health IT. However, we estimated some costs for reviewers who reviewed this final rule. We estimated those costs to be \$1,293,508 in total for an estimated 616 reviewers, which include developers, medical associations, and other health and health IT community members. We did not quantify benefits for this final rule and instead rely on our calculation of cost savings to developers of certified health IT to quantify in dollars the time and effort developers would have

⁷ Section 13111 and 13112 of the HITECH Act requires health IT systems and products to utilize standards adopted under section 3004 of the PHSA in specified circumstances. The HHS Health IT Alignment Program, led by ONC builds upon the HITECH to advance interoperability across HHS investments. See <https://www.healthit.gov/topic/hhs-health-it-alignment-program>.

⁸ <https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement>.

expended had these requirements remained in effect in perpetuity. In total, consistent with analytic guidance on E.O. 14192, this finalized rulemaking would result in a present value of cost savings of \$1.55 billion and annualized net cost savings of \$108.1 million in 2024 dollars and discounted at a rate of 7%, beginning in 2027 and in perpetuity.

II. Background

A. Statutory Basis

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created “Title XXX—Health Information Technology and Quality” (Title XXX) to improve healthcare quality, safety, and efficiency through the promotion of health IT and electronic health information (EHI) exchange.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was enacted on December 13, 2016, to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes. The Cures Act, through Title IV—Delivery, amended the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

1. Standards, Implementation Specifications, and Certification Criteria

The HITECH Act established two Federal advisory committees, the Health IT Policy Committee (HITPC) and the Health IT Standards Committee (HITSC). Each was responsible for advising the National Coordinator for Health Information Technology (National Coordinator) on different aspects of standards, implementation specifications, and certification criteria.

Section 4003(e) of the Cures Act amended sections 3002 and 3003 of the PHSA by replacing, in an amended section 3002, the HITPC and HITSC with one committee named the Health Information Technology Advisory Committee (Health IT Advisory Committee or HITAC). Section 3002(a) of the PHSA, as added by the Cures Act, establishes that the HITAC recommends to the National Coordinator policies and standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access,

exchange, and use of health information. Further described in section 3002(b)(1) of the PHSA, this includes recommending to the National Coordinator a policy framework to advance interoperable health information technology infrastructure, updating recommendations to the policy framework, and making new recommendations, as appropriate. Section 3002(b)(2)(A) of the PHSA specifies that in general, the HITAC shall recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Like the process previously required of the former HITPC and HITSC, section 3002(b)(5) of the PHSA requires the HITAC to develop a schedule, updated annually, for the assessment of policy recommendations, which the Secretary publishes in the **Federal Register**.⁹

Section 3004 of the PHSA establishes a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator in section 3001(c) and subsequently determine whether to propose the adoption of such standards, implementation specifications, or certification criteria. Section 3004(a)(3) requires the Secretary to publish all such determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, titled Subsequent Standards Activity, provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the HITAC. We consider this provision in the broader context of the HITECH Act and Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been

recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria.

2. Health IT Certification Program(s)

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of health IT. Section 3001(c)(5)(A) specifies that the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology (NIST), shall keep or recognize a program or programs for the voluntary certification of health IT that is in compliance with applicable certification criteria adopted in section 3004 of the PHSA.

The certification program(s) must also include, as appropriate, testing of the technology in accordance with section 13201(b) of the HITECH Act. Overall, section 13201(b) of the HITECH Act requires that, with respect to the development of standards and implementation specifications, the Director of NIST shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The HITECH Act also indicates that the development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.

Section 4002(a) of the Cures Act amended section 3001(c)(5) of the PHSA by adding section 3001(c)(5)(D), which requires the Secretary, through notice-and-comment rulemaking, to require conditions of certification and maintenance of certification for the Certification Program. Specifically, the health IT developers or entities with technology certified under the Certification Program must, in order to maintain such certification status, adhere to certain conditions and maintenance of certification requirements concerning information blocking; assurances regarding appropriate exchange, access, and use of electronic health information; communications regarding health IT; APIs; real world testing; attestations regarding certain conditions and maintenance of certification requirements; and submission of reporting criteria under the EHR Reporting Program in accordance with section 3009A(b) of the PHSA.

⁹ See, e.g., “Health Information Technology Advisory Committee Schedule of Meetings” (91 FR 2542). <https://www.federalregister.gov/documents/2026/01/21/2026-01046/health-information-technology-advisory-committee-schedule-of-meetings>.

B. ONC Health IT Certification Program Regulatory History

The Secretary issued an interim final rule with request for comments on January 13, 2010, “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” (the “S&CC January 2010 Interim Final Rule”) (75 FR 11328), which adopted an initial set of standards, implementation specifications, and certification criteria. On March 10, 2010, the Secretary issued a proposed rule, “Proposed Establishment of Certification Programs for Health Information Technology” (75 FR 11328), that proposed both temporary and permanent certification programs for the purposes of testing and certifying health IT. A final rule establishing the temporary certification program was published on June 24, 2010, “Establishment of the Temporary Certification Program for Health Information Technology” (75 FR 36158), and a final rule establishing the permanent certification program was published on January 7, 2011, “Establishment of the Permanent Certification Program for Health Information Technology” (76 FR 1262).

After consideration of the comments received on the S&CC January 2010 Interim Final Rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for the EHR Incentive Programs Stage 1, titled “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” (75 FR 44590, July 28, 2010) (2011 Edition Final Rule). The 2011 Edition Final Rule also established the first version of the certified electronic health record technology (CEHRT) definition. Subsequent to the 2011 Edition Final Rule, on October 13, 2010, we issued an interim final rule “Health Information Technology: Revisions to Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology” with a request for comment to remove certain implementation specifications related to public health surveillance that had been previously adopted in the 2011 Edition Final Rule (75 FR 62686).

The standards, implementation specifications, and certification criteria adopted by the Secretary in the 2011 Edition Final Rule established the capabilities that CEHRT must include in

order to, at a minimum, support the achievement of EHR Incentive Programs Stage 1 by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) under the “Medicare and Medicaid Programs; Electronic Health Record Incentive Program” final rule (75 FR 44314, July 28, 2010) (EHR Incentive Programs Stage 1 Final Rule).

On March 7, 2012, the Secretary issued a proposed rule with request for comments titled “Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology” (77 FR 13832) (2014 Edition Proposed Rule), which proposed new and revised standards, implementation specifications, and certification criteria.

After consideration of the comments received on the 2014 Edition Proposed Rule, a final rule titled “Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology” (77 FR 54163) (2014 Edition Final Rule) was issued on September 4, 2012, to adopt the 2014 Edition set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for the EHR Incentive Programs Stage 2, as well as Stage 1 revisions. The 2014 Edition Final Rule adopted a proposal to change the Permanent Certification Program’s name to the “ONC HIT Certification Program,” revised the process for permitting the use of newer versions of “minimum standard” code sets, modified the certification processes ONC–ACBs need to follow for certifying EHR Modules in a manner that provides clear implementation direction and compliance with the new certification criteria, and eliminated the certification requirement that every EHR Module be certified to the “privacy and security” certification criteria.

The standards, implementation specifications, and certification criteria adopted by the Secretary in the 2014 Edition Final Rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of the EHR Incentive Programs Stage 2 by EPs, eligible hospitals, and CAHs under the “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2” final rule (77 FR

53968, September 4, 2012) (EHR Incentive Programs Stage 2 Final Rule).

On December 7, 2012, an interim final rule with a request for comment, titled “Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program” (77 FR 72985), was jointly issued and published by ONC and CMS to update certain standards that had been previously adopted in the 2014 Edition Final Rule. The interim final rule also revised the EHR Incentive Programs by adding an alternative measure for the Stage 2 objective for hospitals to provide structured electronic laboratory results to ambulatory providers, corrected the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission, and made the case number threshold exemption policy for clinical quality measure (CQM) reporting applicable for eligible hospitals and CAHs beginning with FY 2013. In addition, the interim final rule provided notice of CMS’ intent to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012. On September 4, 2014, a final rule “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards” (79 FR 52910) was published adopting these proposals.

On November 4, 2013, the Secretary published an interim final rule with a request for comment titled “2014 Edition Electronic Health Record Certification Criteria: Revision to the Definition of ‘Common Meaningful Use (MU) Data Set’” (78 FR 65884) to make a minor revision to the Common MU Data Set definition. This revision was intended to allow more flexibility with respect to the representation of dental procedures data for EHR technology testing and certification.

On February 26, 2014, the Secretary published a proposed rule titled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements” (79 FR 10880) (“Voluntary Edition Proposed Rule”). The proposed rule proposed a voluntary edition of certification criteria that was designed to enhance

interoperability, promote innovation, and incorporate “bug fixes” to improve upon the 2014 Edition. The Voluntary Edition Proposed Rule also included proposals that focused on improving regulatory clarity, simplifying the certification of EHR Modules that are designed for purposes other than meeting requirements of the EHR Incentive Programs, and discontinuing the use of the Complete EHR definition. A correction notice was published for the Voluntary Edition Proposed Rule on March 19, 2014, entitled “Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements; Correction” (79 FR 15282). This correction notice corrected the preamble text and gap certification table for four certification criteria that were omitted from the list of certification criteria eligible for gap certification for the 2015 Edition EHR certification criteria. On September 11, 2014, a final rule was published titled “2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange” (79 FR 54430) (2014 Edition Release 2 Final Rule). The final rule adopted a small subset of the original proposals in the Voluntary Edition Proposed Rule as optional and revised 2014 Edition EHR certification criteria that provide flexibility, clarity, and enhance health information exchange. It also finalized administrative proposals (*i.e.*, removal of regulatory text from the CFR) and proposals for the ONC HIT Certification Program that provide improvements. We issued the 2014 Edition Release 2 Final Rule to complete the rulemaking for the Voluntary Edition Proposed Rule. The 2014 Edition Release 2 Final Rule discontinued the “Complete EHR” certification concept beginning with the proposed 2015 Edition, adopted an updated standard (ISO/IEC 17065) for the accreditation of ONC-ACBs, and adopted the “ONC Certified HIT” certification and design mark for required use by ONC-ACBs under the Certification Program.

On May 23, 2014, CMS and ONC jointly published a proposed rule titled “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition” (79 FR 29732). The proposed rule proposed to update the EHR Incentive Programs Stage 2 and

Stage 3 participation timeline. It proposed to revise the CEHRT definition to permit the use of EHR technology certified to the 2011 Edition to meet the CEHRT definition for FY/CY 2014. It also proposed to allow EPs, eligible hospitals, and CAHs that could not fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 due to delays in the availability of such technology to continue to use EHR technology certified to the 2011 Edition or a combination of EHR technology certified to the 2011 Edition and 2014 Edition for the EHR reporting periods in CY 2014 and FY 2014. On September 4, 2014, a final rule titled “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards” (CEHRT Flexibility Final Rule) was published (79 FR 52910) adopting these proposals.

On March 30, 2015, the Secretary published a proposed rule titled “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” (80 FR 16804) (2015 Edition Proposed Rule). The 2015 Edition Proposed Rule proposed revisions to the Certification Program with a revised edition of certification criteria that was designed to enhance interoperability.

On October 16, 2015, the Secretary published a final rule titled “2015 Edition Health Information (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” (80 FR 62602) (2015 Edition Final Rule). The 2015 Edition Final Rule established a new edition of certification criteria (2015 Edition) and a new 2015 Edition Base EHR definition. CMS subsequently established that the 2015 Edition Base EHR definition encompassed the minimum capabilities and the related minimum standards and implementation specifications that CEHRT would need to include to support the achievement of “meaningful use” by eligible clinicians, eligible hospitals, and CAHs under the Medicare and Medicaid EHR Incentive Programs (the predecessors to the Medicare Promoting Interoperability Program and the Promoting Interoperability performance category under the Merit-based Incentive Payment System

(MIPS)). The final rule also adopted a proposal to change the Certification Program’s name to the “ONC Health IT Certification Program” from the ONC HIT Certification Program, modified the Certification Program to make it more accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond the ambulatory and inpatient settings, and adopted new and revised Principles of Proper Conduct (PoPC) for ONC-ACBs. A final rule making corrections and clarifications was published for the 2015 Edition Final Rule (80 FR 76868) on December 11, 2015, to correct preamble and regulatory text errors and clarify requirements of the CCDS, the 2015 Edition privacy and security certification framework, and the mandatory disclosures for health IT developers.

After issuing a proposed rule on March 2, 2016, “ONC Health IT Certification Program: Enhanced Oversight and Accountability” (81 FR 11056), we published a final rule by the same title (81 FR 72404) (EOA Final Rule) on October 19, 2016. The EOA Final Rule finalized modifications and new requirements under the Certification Program, including provisions related to our role in the Certification Program. The EOA Final Rule created a regulatory framework for our direct review of health IT certified under the Certification Program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the Certification Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The final rule also set forth processes for us to authorize and oversee accredited testing laboratories under the Certification Program. In addition, it included provisions for expanded public availability of certified health IT surveillance results.

On March 4, 2019, the Secretary published a proposed rule titled “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” (84 FR 7424) (Cures Act Proposed Rule). The proposed rule proposed to implement certain provisions of the 21st Century Cures Act (Cures Act) that would advance interoperability and support the access, exchange, and use of electronic health information.

On May 1, 2020, the “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” (Cures Act Final Rule) was published in the **Federal Register** (85 FR 25642). The final rule

implemented certain provisions of the Cures Act, including Conditions and Maintenance of Certification requirements for health IT developers, the voluntary certification of health IT for use by pediatric health providers, and reasonable and necessary activities that do not constitute information blocking. The final rule modified the 2015 Edition health IT certification criteria and Certification Program in other ways to advance interoperability, enhance health IT certification, and reduce burden and costs, as well as to improve patient and health care provider access to EHI and promote competition. On November 4, 2020, the Secretary published an interim final rule with comment period titled “Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency” (85 FR 70064) (Cures Act Interim Final Rule). The interim final rule extended certain compliance dates and timeframes adopted in the Cures Act Final Rule to offer the healthcare system additional flexibilities in furnishing services to combat the COVID-19 pandemic.

On April 18, 2023, the Secretary published a proposed rule titled “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” (88 FR 23746) (HTI-1 Proposed Rule). The HTI-1 Proposed Rule proposed to implement the EHR Reporting Program provision of the Cures Act by establishing new Conditions and Maintenance of Certification requirements for health IT developers under the Certification Program. The HTI-1 Proposed Rule also proposed several updates to certification criteria and implementation specifications recognized by the Certification Program, including revised certification criteria for: “clinical decision support,” “patient demographics and observations,” and “electronic case reporting.” The HTI-1 Proposed Rule also proposed to establish a new baseline version of the United States Core Data for Interoperability (USCDI).

On January 9, 2024, the Secretary issued the “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” final rule (HTI-1 Final Rule), which implemented the EHR Reporting Program provision of the 21st Century Cures Act and established new Conditions and Maintenance of Certification requirements for health IT developers under the Certification

Program (89 FR 1192). The HTI-1 Final Rule also made several updates to certification criteria and standards recognized by the Certification Program. The Certification Program updates included revised certification criteria for “decision support interventions” (DSIs) and “electronic case reporting,” as well as adopted a new baseline version of the USCDI standard, USCDI Version 3 (v3). Through these provisions, we sought to advance interoperability, improve algorithm transparency, and support the access, exchange, and use of EHI. The HTI-1 Final Rule also updated numerous technical standards in the Certification Program to advance interoperability, enhance health IT certification, and reduce burden and costs for health IT developers and users of health IT.

On August 5, 2024, the Secretary published a proposed rule titled “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability” (89 FR 63498) (HTI-2 Proposed Rule). The HTI-2 Proposed Rule sought to advance interoperability, improve transparency, and support the access, exchange, and use of EHI through proposals for: standards adoption; adoption of certification criteria to advance public health data exchange; expanded uses of certified APIs, such as for electronic prior authorization, patient access, care management, and care coordination; and information sharing under the information blocking regulations. Additionally, the HTI-2 Proposed Rule proposed to establish a new baseline version of the USCDI standard and proposed to update the Certification Program to enhance interoperability and optimize certification processes to reduce burden and costs. The HTI-2 Proposed Rule also proposed to implement certain provisions related to the Trusted Exchange Framework and Common Agreement (TEFCA), which would support the reliability, privacy, security, and trust within TEFCA.

On December 16, 2024, the Secretary issued the “Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (TEFCA)” final rule (89 FR 101772) (HTI-2 Final Rule) which implemented advancements to interoperability, improved transparency, and supported the access, exchange, and use of electronic health information. The HTI-2 Final Rule codified definitions of certain TEFCA terms in § 171.401 of the information blocking regulations and finalized the 45 CFR part 172 TEFCA provisions.

On July 31, 2025, ONC finalized the “Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization” final rule (90 FR 37130) (HTI-4 Final Rule), as a part of the “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization” (FY 2026 IPPS/LTCH PPS Final Rule), published by CMS on August 4, 2025 (90 FR 36536). The HTI-4 Final Rule finalized a limited subset of the proposals in the HTI-2 Proposed Rule (89 FR 63498) and focused on improving care delivery and reducing administrative burden through the exchange of clinical and administrative information. The HTI-4 Final Rule updated the ONC Health IT Certification Program to add several new certification criteria that advance health care providers’ ability to engage in electronic prescribing, real-time prescription benefit checks, and electronic prior authorization.

On December 29, 2025, the Secretary issued a withdrawal of non-finalized provisions titled, “Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal” (90 FR 60602) (HTI-2 Withdrawal Notice). The HTI-2 Withdrawal Notice withdrew the remaining proposals that have not been finalized from the HTI-2 Proposed Rule.

On December 29, 2025, the Secretary published the “Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity” Proposed Rule (90 FR 60970) (Proposed Rule). The Proposed Rule focused on deregulatory actions identified in HHS regulations regarding health IT standards, implementation specifications, certification criteria and certification programs for health IT, and information blocking. The Proposed Rule sought to reduce burden, offer flexibility to both developers and providers, and support innovation through the removal and revisions of certain certification criteria and regulatory provisions.

C. General Comments on the Proposed Rule

Comments. Many commenters were supportive of modernizing the Certification Program around FHIR-based APIs and reducing outdated or duplicative requirements, stating that it would have the benefit of reducing administrative burden, improving standards-based interoperability, and supporting automation, innovation, and more scalable exchange. They also noted that this modernization would allow vendors and implementers to redirect effort away from low-value compliance activities and toward real-world interoperability, reliability, scalability, and more granular exchange. Some of these commenters emphasized that a “FHIR-forward” approach should advance computable interoperability, where exchanged data are reliably structured, attributable, and usable, not simply accessible. The commenters noted that this would reduce integration burden, improve data quality, and accelerate innovation across care delivery, payer, public health, and third-party application ecosystems.

Response. We thank commenters for their support for America’s FHIR-forward future. We may take these comments into consideration to inform future rulemaking.

Comments. We received numerous comments that were not supportive of the deregulatory approach to reducing or removing certification and related interoperability guardrails without replacement safeguards. These commenters expressed significant concerns that such approaches would weaken baseline functionality, increase fragmentation and cost, and shift operational, compliance, and financial burdens to providers, public health agencies, and other end users. Some of these commenters expressed concerns that when foundational capabilities are no longer required, they reappear as optional modules, implementation fees, or premium features that providers must purchase to achieve necessary functionality. A commenter recommended prompt release of the next future rulemaking stating difficulties commenting on the Proposed Rule without knowing future plans for the Certification Program. These commenters noted that our proposal for a transition toward a FHIR-based API ecosystem would require additional guidance or specification of phased timelines, readiness thresholds, implementation best practices, testing and performance expectations, and the continued role of existing exchange pathways during transition.

Some commenters highlighted that many organizations continue to operate in a hybrid environment where document-based exchange remains foundational to many workflows. Several commenters also warned that, absent a required, standardized, and patient-accessible FHIR-native alternative, removal of Consolidated Clinical Document Architecture (C-CDA)-based summary functionality could leave patients and caregivers with technically complete but clinically fragmented information during care transitions. Many of these commenters also expressed similar concerns in relation to specific proposals, which we address in their respective sections throughout this final rule.

A couple of commenters urged ONC to be mindful of financial and workforce strain on rural and other low-resourced providers. Commenters suggested ONC create grants for small and rural providers to implement APIs and electronic health record upgrades. Another commenter requested clarification on whether the rule limits State authority to require certain standards if certification no longer guarantees certain capabilities.

Response. We thank commenters for their feedback. We first clarify that the removal of certain certification criteria does not limit State authority as States remain able to establish their own requirements as permitted by law. Generally, we note that these concerns are likely mitigated by our final decisions to retain the majority of certification criteria and to give additional transition time for certain C-CDA certification criteria. In addition, we have further addressed these comments in section III below as they relate to specific proposals to remove criteria or functionality. We have also addressed timelines for certification criteria relevant to the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category in their respective sections.

We acknowledge commenters’ concerns that capabilities no longer included in the Certification Program could be offered as optional or premium features. The purpose of the Certification Program is to establish the minimum criteria that health IT must meet to obtain certification. We do not believe that users will see a significant increase in overall costs because the costs for certain functionalities were likely included in the costs that customers currently pay to use a particular certified Health IT Module. As noted by commenters, functionalities associated with removed criteria were

part of the certified Health IT Module that a customer purchased or licensed for a fee, which presumably included the costs of the functionality. To the extent that health IT developers continue to charge for specified functionalities, customers may now be able to see the cost of a specific functionality independent of the certified Health IT Modules, providing further price transparency to the decision-making and purchasing processes.

Comments. Another commenter recommended that ONC provide technical assistance and develop model contracting/procurement tools (e.g., model contract language and BAA provisions) to help under-resourced providers preserve capabilities if certification requirements are removed.

Response. While this comment is generally out of scope, we direct readers to the EHR Contract Guide.¹⁰

Comments. A commenter suggested that ONC remove any certification criteria by enforcement discretion to allow for maximum flexibility rather than the proposed timelines to reduce confusion regarding the timing of when to seek certification.

Response. In response to the commenter suggesting removing certification criteria by enforcement discretion, we emphasize that use of enforcement discretion does not remove a regulatory requirement. Rather, it provides regulated entities with assurance that they will not be found nonconformant or non-compliant with regulatory provisions for a temporary period of time. Consideration of public feedback and ultimately finality is achieved through notice and comment rulemaking.

Comments. Some commenters requested we publish a consolidated, executable implementation plan or roadmap and guidance to transition to HL7® FHIR®, especially for rural providers, and State, Tribal, Local, and Territorial (STLT) public health authorities (PHAs), who remain dependent on C-CDA based criteria for data exchange. A couple of commenters also recommended providing clear, consolidated implementation guidance for ONC-ACBs and ONC-ATLs, particularly on the operational side during the transition.

Response. We maintain a web page dedicated to HL7® FHIR®, which includes a draft FHIR Action Plan among many other resources related to

¹⁰ https://healthit.gov/wp-content/uploads/2025/03/EHR_Contracts_Untangled.pdf.

HL7® FHIR® maturity and use cases.¹¹ We also have an upcoming planned regulatory action that will focus on HL7® FHIR® based exchange.¹² Ultimately, the regulatory process provides for public input that informs actual requirements that can be relied upon for investments and implementation.

D. Comments Beyond the Scope of Certification Program Proposals

Comments. We received numerous comments that were out of scope for this rulemaking including, but not limited to, the following comments. Some commenters recommended that our proposals for future API-focused policies should require specification of endpoint discovery and onboarding, implementation consistency, write capabilities, performance expectations, alignment with existing frameworks and public health workflows, as well as guardrails regarding fees, rate limiting, contracting delays, and enforcement. A few of these commenters recommended ONC to publish all regulated FHIR API endpoints in a single publicly available location or directory.

Many commenters suggested additional future rulemaking goals and policies including support for real-time bi-directional exchange, standardized value sets, digital identity, and further support for clinical efficiency, patient access, public health reporting, data quality using rubrics and frameworks, quality measurement and reporting, and bulk data access and support. Commenters also opined on SI oversight, TEFGA policies, and CMS Programs.

Response. We thank commenters for their input and interest in future rulemaking. These comments are out of scope for the Proposed Rule in that we did not propose any new standard, certification criteria, and requirements in this rulemaking. Comments regarding CMS program requirements are also out of scope as ONC does not have direct authority to change CMS policy. We refer readers to CMS programs for further information.

III. Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology (Part 170)

Reading This Final Rule

In this preamble, we present our finalizations in an order that begins with the certification criteria we finalized for removal and subsequently the standards, definitions, and other related Certification Program provisions finalized for removal or revision. This approach should make it easier for readers to follow our finalized Certification Program removals, in part, due to the natural cascading effects of finalizing to remove or revise a certification criterion.

Additionally, we finalized the removal of standards when they are no longer referenced by existing certification criteria. In very limited circumstances, we retained a standard that is cross-referenced in a certification criterion that we finalized for removal. We did this because the standard is cross-referenced in another criterion and/or supports health IT interoperability alignment. Further, as noted above, we finalized the removal of certain Conditions and Maintenance of Certification requirements and other Certification Program requirements.

As stated above, for the purposes of this final rule, we have reviewed and responded to comments on a narrowed set of proposals from the Proposed Rule. Comments received in response to other Proposed Rule proposals remain under review and consideration. The Proposed Rule proposals not discussed in this final rule may, in the future, be included in subsequent final rules or as revised proposals in subsequent proposed rules.

RFI Feedback

Recently, the Office of Management and Budget (OMB), the Department, and CMS–ONC issued requests for information (RFIs) related to deregulation. We reviewed comments related to ONC. In response to the CMS–ONC Request for Information; Health Technology Ecosystem (90 FR 21034) (CMS–ONC RFI), commenters expressed a strong desire to modernize the Certification Program to be more modular, API-focused, and less centered on specific EHR functionalities. Commenters recommended simplifying the process, reducing costs, and expanding certification requirements to ensure payers and other health IT systems adhere to the same interoperability standards. There was an

overwhelming demand to strengthen, expand, and mandate the use of FHIR-based APIs. Commenters strongly advocated for retiring outdated, less efficient standards to reduce complexity. A central theme from commenters was the need for regulatory modernization to reduce administrative and financial burdens on providers and technology developers. Commenters also expressed concern that existing certification requirements are often too rigid, costly, and not aligned with emerging care models like value-based care or specialized technologies such as SI and remote monitoring. A commenter that responded to the HHS RFI expressed concerns with the Real World Testing and Insights Conditions of Certification, stating that the requirements are overly burdensome and offer limited value to providers or patients. The commenter also recommended retiring low-value certification criteria requirements that add complexity without improving care. A commenter that responded to the OMB RFI suggested that revisions could be made to the Conditions and Maintenance of Certification requirements that focus on streamlined and meaningful oversight without placing undue demands on developers, especially where those demands offer limited direct benefit to health care provider customers or their patients. The commenter also suggested the removal of “non-interoperability-focused, redundant, or valueless” criteria and a focus on promoting standardized and scalable interoperability. ONC addresses a number of these comments below, specifically the suggestions to remove non-interoperability-focused and non-essential certification criteria. Commenters were strongly supportive of our focus on FHIR-based standards. Some commenters, however, included suggestions related to new regulatory actions. As noted in the Proposed Rule, these suggestions are out of scope for this deregulatory rule, but we may consider the suggestions for a future rulemaking (90 FR 60979).

A. Certification Criteria for Health Information Technology

In this final rule we have identified certification criteria for removal or revision. For some of the certification criteria below, we justify removing the certification criteria because they have been “widely adopted” or “widely implemented.” To determine if the certification criterion is “widely adopted” or “widely implemented,” we considered whether and for how long the certification criterion has been

¹¹ <https://healthit.gov/interoperability/investments/fhir/>.

¹² <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202510&RIN=0955-AA10>.

included in the Base EHR definition in § 170.102, or the Certified Electronic Health Record Technology (CEHRT) definitions established by CMS in 42 CFR 495.4 and 414.1305. The CEHRT definitions incorporate the Base EHR definition and may also incorporate certification criteria necessary to report applicable objectives and measures under the Medicare Promoting Interoperability Program or the Promoting Interoperability performance category in the Merit-based Incentive Payment System (MIPS), certification criteria determined applicable for an Alternative Payment Model (APM), and other certification criteria as specified. To participate in the Promoting Interoperability Program and the MIPS Promoting Interoperability performance

category, eligible hospitals, CAHs, and eligible clinicians must use CEHRT as specified by the applicable definition. In addition, CEHRT is required for the purposes of determinations under 42 CFR 414.1415 and 414.1420 regarding Advanced APM status. ONC tracks and publishes data on the adoption and use of health IT, including CEHRT, by US hospitals and office-based physicians. Our most recent survey data from 2024 shows that 99 percent of hospitals and 91 percent of physicians reported having a certified EHR.¹³ As discussed in more detail below, we provide this analysis and consider certain

¹³ <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>.

certification criteria as “widely adopted” or “widely implemented” because they are included in the Base EHR or CEHRT definitions and adopted by 99 and 91 percent of hospitals and physicians, respectively. The certification criteria finalized for removal or revision are also consistent with our drive toward and our support for the FHIR standard as mentioned above in section I.A and are responsive to comments we received on the recently issued RFIs. We explain the proposals we have finalized in detail in their respective sections of the preamble and have provided a table (see Table 1) for a list of all certification criteria finalized for removal and revision.

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Table 1. Certification Criteria Finalized for Removal or Revision

Certification Criteria	Reference	Remove/Revise	Timing
Clinical decision support	§ 170.315(a)(9)	Remove	Effective date of final rule
Family health history	§ 170.315(a)(12)	Remove	Effective January 1, 2027
Transitions of care	§ 170.315(b)(1)	Revise	Effective January 1, 2030
Clinical information reconciliation and incorporation	§ 170.315(b)(2)	Revise	Effective date of final rule
Security tags - summary of care - send	§ 170.315(b)(7)	Remove	Effective date of final rule
Security tags - summary of care - receive	§ 170.315(b)(8)	Remove	Effective date of final rule
Care plan	§ 170.315(b)(9)	Remove	Effective date of final rule
Decision support interventions	§ 170.315(b)(11)	Revise	Effective date of final rule
Clinical quality measures — report	§ 170.315(c)(3)	Revise	Effective date of final rule
Clinical quality measures — filter	§ 170.315(c)(4)	Remove	Effective January 1, 2027
View, download, and transmit to 3rd party	§ 170.315(e)(1)	Revise	Effective date of final rule
Patient health information capture	§ 170.315(e)(3)	Remove	Effective January 1, 2027
Transmission to public health agencies — antimicrobial use and resistance reporting	§ 170.315(f)(6)	Revise	Effective date of final rule
Automated numerator recording	§ 170.315(g)(1)	Remove	Effective January 1, 2027
Automated measure calculation	§ 170.315(g)(2)	Remove	Effective January 1, 2027

Safety-enhanced design	§ 170.315(g)(3)	Revise	Effective date of final rule
Consolidated CDA creation performance	§ 170.315(g)(6)	Remove	Effective date of final rule
Application access — patient selection	§ 170.315(g)(7)	Remove	Effective January 1, 2027
Application access — all data request	§ 170.315(g)(9)	Remove	Effective January 1, 2027
Direct Project	§ 170.315(h)(1)	Remove	Effective date of final rule
Direct Project, Edge Protocol, and XDR/XDM	§ 170.315(h)(2)	Remove	Effective date of final rule

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1. Clinical Certification Criteria

a. Clinical Decision Support

As of January 1, 2025, the “clinical decision support” (CDS) certification criterion in § 170.315(a)(9) is no longer available in the Certification Program because it expired on January 1, 2025 (89 FR 1237). Therefore, in the Proposed Rule, we proposed to remove the CDS certification criterion and reserve § 170.315(a)(9) with an effective date of a final rule (90 FR 60982).

Comments. Commenters who supported the proposal to remove the CDS certification criterion shared that it would clean up outdated requirements without affecting current certification pathways and promote innovation given that the certification criterion has expired or been superseded by decision support interventions.

Response. We thank the commenters for their support on this proposal. We agree that removing § 170.315(a)(9) from the CFR will clean up outdated requirements without affecting current certification pathways and will promote innovation.

Comments. Of the commenters who were not supportive of this proposal, some expressed concerns that it would weaken patient safety safeguards, reduce transparency and accountability, and shift oversight and implementation burdens to providers and healthcare organizations. Another commenter urged ONC to delay removal until 2028 to achieve cross-agency, harmonized standards. Some commenters conveyed that our proposal for removing the certification criterion would require additional guidance or specification of how transparency requirements would be preserved if § 170.315(a)(9) is

removed or if source attribute requirements are removed from § 170.315(b)(11).

Response. We thank the commenters for their feedback on this proposal. In response to comments that appeared to connect our proposal in § 170.315(a)(9) with our proposals in § 170.315(b)(11), we remind readers that in the HTI-1 Final Rule we originally expired the CDS certification criterion effective January 1, 2025 (89 FR 1430). At the time, we declined commenters’ request to extend the expiration date noting that it will not move the Certification Program forward. CDS is an expired certification criterion that is no longer available in the Certification Program and health IT developers have been unable to certify their health IT products to CDS since January 1, 2025. Therefore, removing § 170.315(a)(9) from the CFR will not result in any further substantive effects, and delaying its removal is unnecessary.

We appreciate commenters’ requests for guidance. However, we do not think guidance is necessary for the removal of an expired certification criterion that is no longer a requirement for certification.

Comments. Some commenters requested that, despite its expiration, we retain (*i.e.*, not remove) the certification criterion in § 170.315(a)(9), reinstate the certification criterion, or use the requirements in the CDS certification criterion in § 170.315(a)(9) instead of the narrower DSI requirements in § 170.315(b)(11) for evidence-based CDS in order to preserve transparency.

Response. We thank the commenters for their suggestions. As noted above, we did not propose in the HTI-5 Proposed Rule to reverse our prior determination to remove the CDS certification criterion and/or reinstate

the CDS certification criterion. Further, in the HTI-1 Final Rule, we stated that it is suitable to implement the CDS certification criterion in § 170.315(a)(9) in a revised version in § 170.315(b)(11) due to the structure of the certification criterion, and that this approach is more straight-forward than having substantially similar yet separate certification criteria (89 FR 1237). Similarly, we issued the Proposed Rule to reduce burden by eliminating redundant requirements and to promote innovation (90 FR 60971). Consistent with this approach, adopting a separate CDS certification criterion in § 170.315(a)(9) with requirements similar to those in § 170.315(b)(11)(iii), which we have revised but not removed from the Certification Program (see section III.A.2.e), would undermine these goals and would not serve the interests of the Certification Program or users of certified health IT. Rather, it would recreate two substantially similar but separate certification criteria, adding complexity and burden to the Certification Program. Accordingly, we have finalized the removal of § 170.315(a)(9) CDS certification criterion from the CFR and reserved that section as proposed as of the effective date of this final rule.

In section III.A.2.e of this final rule, we note that we have finalized removal of the requirements in § 170.315(b)(11)(iv). As a result, some elements that were similar between § 170.315(a)(9) and § 170.315(b)(11)(iv) have been removed from the Certification Program. As noted in that section of the preamble of this final rule, we will take under consideration for future rulemaking whether such elements of “source attributes

transparency” should be restored to the DSI certification criterion.

b. Family Health History

In the Proposed Rule (90 FR 60982 through 60983), we proposed to remove the “family health history” certification criterion and reserve § 170.315(a)(12). We explained that Health IT Modules certified to § 170.315(a)(12) must enable a user to record, change, and access a patient’s family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in § 170.207(a)(1) (SNOMED CT®, U.S. Edition, March 2022 Release). We noted that this certification criterion is not included in the Base EHR definition in § 170.102 but is included in the CEHRT definitions established by CMS for the Medicare Promoting Interoperability Program (42 CFR 495.4) and the MIPS Promoting Interoperability performance category (42 CFR 414.1305). Therefore, we proposed a January 1, 2027, effective date for its removal to allow sufficient time for CMS to update the CEHRT definitions.

Comments. Some commenters expressed support for the proposal to remove the family health history certification criterion. These commenters agreed that the family health history functionality is already well established in certified health IT and that it is likely to remain available through existing product capabilities or evolving data standards. Some commenters opined that exchange data standards can replace “functional” certification requirements, and retaining the family health history is duplicative of the requirements in USCDI v6. Another commenter expressed that, with appropriate USCDI and interoperability-based certification policies, removing the standalone family health history certification criterion would not affect the quality or integrity of the Certification Program. Another commenter noted that retaining the certification criterion is unnecessary because it is not cited in the Qualified EHR definition.

Response. We thank the commenters for their support of the proposal. We appreciate the commenters feedback on the removal of this certification criterion from the Certification Program. We have finalized our proposal to remove the family health history certification criterion from the CFR and we have reserved § 170.315(a)(12), with an effective date of January 1, 2027. We address other comments received on this proposal below.

Comments. The majority of comments received on our proposal to remove the

family health history certification criterion generally did not support the proposal. Many commenters, including several community health centers, expressed significant concerns that it would reduce structured, standardized capture of family health history and thereby impair interoperability, clinical decision support, preventive care, and population health activities. Some commenters also raised concerns that the proposal is premature, would increase manual burden, lead to inconsistent implementations, and reduce data quality. Commenters also asserted that removal could shift burden to health care providers.

Response. We thank commenters for their feedback. The retention of the family health history certification criterion in the Certification Program would not support our stated goal of advancing interoperability because it is a non-FHIR-based certification criteria (90 FR 60972 through 60973) and only focuses on internal capabilities to record, change, and access family health history according to the SNOMED CT® U.S. Edition standard. However, we note that the removal of the family health history certification criterion does not impact existing functionality within implemented systems, and does not remove the Family Health History data element from use and reference within standards adopted for the Certification Program. Instead, the removal of the family health history certification criterion is consistent with our goal to transition to FHIR-based exchange, as demonstrated by the inclusion of Family Health History data elements in USCDI v6¹⁴ and the HL7® FHIR® US Core Implementation Guide (IG) 9.0.0—CI Build.¹⁵ Representing these data in FHIR as part of the US Core IG is a more effective way to ensure these data are widely available not only for access, but also for exchange and use to improve patient care. This approach not only maintains but enhances the ability to leverage family health history for clinical decision support, preventive care, and population health activities by promoting standardized, interoperable data exchange.

As we discussed in the Proposed Rule, the functionality included in the family health history certification criterion (capability to capture family health history according to SNOMED CT® U.S. Edition) has been widely adopted by hospitals and physicians (90

FR 60979 through 60980). Thus, we disagree that there is a shift in burden from developers to health care providers because this functionality is well-integrated into existing health IT products, and we do not anticipate that health care providers will experience changes related to this functionality in the health IT products they use.

Similarly, removing the family health history certification criterion will have minimal impact on data consistency because many developers of certified health IT will continue to conform to the SNOMED CT® U.S. Edition standard and the functionality to code family health history with this standard will likely remain in certified health IT adopted by hospitals and physicians (90 FR 60982). Moreover, the updates to USCDI v6 demonstrates ONC’s commitment to the exchange of family health history information using the SNOMED CT® U.S. Edition standard. We note that while USCDI v6 has not been adopted in regulation at this time, as of August 29, 2026, health IT developers participating in the Certification Program may voluntarily use the 2026 SVAP-approved standards, which include USCDI v6, in their certified Health IT Modules.¹⁶ Accordingly, health IT developers may voluntarily update their certified Health IT Modules to USCDI v6 to support family health history information exchange (90 FR 60983).

Regarding commenters’ concerns about data quality related to removing the family health history certification criterion, we clarify that we work directly with HL7® to finalize HL7® FHIR® US Core and C-CDA specifications for each published version of USCDI, including USCDI v6. Where appropriate, these specifications include standardized code systems, such as SNOMED CT® U.S. Edition, that guide which values may be entered for certain data fields. To further support implementation of USCDI v6, we worked with HL7® to update the C-CDA validator and Inferno test tools to align with USCDI v6 and to validate the quality of the data. Consequently, not only will we continue to identify opportunities to work with industry to improve data quality when we publish subsequent versions of USCDI and other standard specifications, but we will also continue to monitor and analyze approaches by health IT developers for real world implementation.

Comments. Some commenters cautioned that the proposal to remove

¹⁴ <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi#draft-uscdi-v6>.

¹⁵ <http://hl7.org/fhir/us/core/ImplementationGuide/hl7.fhir.us.core>.

¹⁶ See <https://healthit.gov/blog/standards/advancements-in-health-it-oncs-2026-approved-svap-standards/>.

this certification criterion may conflict with or complicate CMS program requirements. A few commenters requested that we delay removal until a later rulemaking or until at least 2028 to ensure alignment with CMS between its program requirements and evolving ONC certification criteria. Conversely, another commenter stated we should adopt the removal effective on the effective date of a final rule rather than delaying implementation. Some commenters requested that we provide guidance and sufficient lead time for implementation.

Response. We thank commenters for their feedback regarding alignment with CMS requirements and assure commenters that we work closely with CMS across multiple programs and initiatives on aligning program requirements and deadlines. Consistent with this coordination, we note that in the “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes”¹⁷ proposed rule (FY 2027 IPPS/LTCH PPS proposed rule), CMS proposed to remove the reference to § 170.315(a)(12) in the CEHRT definition in 42 CFR 495.4 (91 FR 19620). On August 4, 2026, CMS published a final rule entitled “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes; and Adoption of Updated Versions of Certain Health Information Technology Standards”¹⁸ (FY 2027 IPPS/LTCH PPS final rule) and finalized the proposed update to the CEHRT definition effective upon the effective date of the FY 2027 IPPS/LTCH

PPS final rule (91 FR 50034 through 50035). CMS also proposed to revise paragraph (2) of the CEHRT definition in 42 CFR 414.1305 to remove reference to § 170.315(a)(12) in the “Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program” proposed rule (CY 2027 PFS proposed rule) (91 FR 43842), which is applicable to the MIPS Promoting Interoperability performance category (91 FR 44169 through 44171). As noted in the Proposed Rule, removing the family health history certification criterion, which does not support a specific CMS program measure, from the Certification Program effective January 1, 2027, provides sufficient time for CMS to update the CEHRT definitions to remove any reference to the certification criterion and allows for alignment with CMS programs (90 FR 60983). Because it is necessary to provide this lead time to CMS and health care providers participating in CMS programs, we decline the recommendation to shorten the effective date timeframe. We will continue to coordinate with CMS on the finalization of proposed updates to regulations as well as future proposals to ensure alignment with the policies we have finalized in this final rule, as well as issuing relevant guidance and informational materials.

Comments. Some commenters expressed opinions regarding the burden reduction that would result from removing this specific certification criterion. These commenters stated that, in practice, the proposal likely does not significantly reduce burden for health IT developers because of the inclusion of the Family Health History data elements in USCDI v6.

Response. We thank the commenters for their input on the burden reduction associated with removing this certification criterion. We acknowledge that removal of the family health history certification criteria may not result in a significant burden reduction. However, the removal of the family health history certification criteria will result in some burden reduction because health IT developers with Health IT Modules certified to § 170.315(a)(12) will no longer need to go through the process of certification to a standalone criterion and maintain updates and conformance to the certification criterion. We maintain that even a modest reduction in burden is more beneficial than maintaining the certification criterion,

and removal can still lead to improved efficiency and cost savings over time. We refer readers to section VII (Regulatory Impact Analysis) for a full discussion on the costs and benefits of our finalized deregulatory actions.

Comments. Several commenters raised concerns about liability exposure as a specific consequence if family history is harder to locate and tied this concern to the possibility of missing clinically significant risk factors.

Response. We thank the commenters for expressing their concerns regarding potential liability exposure if family health history becomes more difficult to obtain, particularly as it relates to the identification of clinically significant risk factors. While we note that whether or not commenters will be exposed to further liability is a question that is outside the scope of this rulemaking, we do not agree that such family health history data would be “harder to locate” because of removal of the family health history certification criterion, as we noted the functionality has widespread implementation and the Family Health History data element is referenced within the USCDI v6 for representation and exchange.

c. Implantable Device List

In the Proposed Rule, we proposed to remove and reserve the “implantable device list” (IDL) certification criterion in § 170.315(a)(14) (90 FR 60983). The IDL certification criterion requires Health IT Modules certified to § 170.315(a)(14) to exchange, record, and allow a user to access a list of Unique Device Identifiers (UDIs) associated with a patient’s implantable devices. There is no adopted standard or implementation guide associated with this functionality. The IDL certification criterion is included in the Base EHR definition, and we proposed a conforming revision in § 170.102 to remove § 170.315(a)(14) from the Base EHR definition (please see section III.C.1 of the Proposed Rule). We proposed to make these changes effective as of the effective date of the final rule (90 FR 60984).

Comments. Of the commenters that specifically commented on this criterion, commenters were generally supportive of removal of the certification criterion, noting that the functionality is well-established, included in USCDI, and that removal would streamline the Certification Program without sacrificing interoperability.

Response. We thank the commenters for expressing their support to remove the IDL certification criterion. We have not, however, finalized our proposal to

¹⁷ “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes.” (91 FR 19312) <https://www.federalregister.gov/d/2026-07203/p-2659>.

¹⁸ “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; Other Policy Changes; and Adoption of Updated Versions of Certain Health Information Technology Standards.” (91 FR 49570). <https://www.federalregister.gov/documents/2026/08/04/2026-15833/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-ipp-and>.

remove the IDL certification criterion (§ 170.315(a)(14)) nor any related proposals such as removing the IDL certification criterion from the Base EHR definition.

Comments. Commenters who were not supportive of removing the IDL certification criterion expressed concerns that removal of the criterion would undermine interoperability, create inconsistency in implementation, and jeopardize patient safety.

Response. We thank the commenters for expressing their concerns, but presume these concerns are moot since we are not removing the IDL certification criterion. Therefore, we are not specifically addressing these concerns.

After publication of the Proposed Rule, CMS proposed, in the FY 2027 IPPS/LTCH PPS proposed rule, to adopt the “Unique Device Identifiers (UDIs) for Implantable Medical Devices” measure within the Public Health and Clinical Data Exchange objective for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. CMS stated that this measure would foster consistent workflows for capturing device data as discrete EHR elements and strengthen the ability of eligible hospitals, CAHs, beneficiaries, and public health agencies to use interoperable health information to improve outcomes, manage risk, and respond rapidly to device-related safety concerns. (91 FR 19629 through 19631). CMS proposed that an eligible hospital or critical access hospital (CAH) must use CEHRT to electronically capture and store, as one or more discrete data elements within the patient’s electronic health record, the complete UDI, which includes the device identifier and, when present on the device label, the production identifier, for each implantable medical device subject to UDI requirements used for patient care delivery. CMS proposed to require eligible hospitals and CAHs to attest to this measure beginning with the EHR reporting period in CY 2027.

In its proposed rule, CMS noted that there are numerous health IT certification criteria that reference UDI, including the IDL certification criterion in § 170.315(a)(14) (91 FR 19631). CMS stated this certification criterion would be required to support the measure. CMS also highlighted our proposal to remove the IDL certification criterion in the Proposed Rule (90 FR 60983) and stated that if ONC finalizes removal of the IDL certification criterion then CMS would not reference the IDL certification criterion as required to support the measure. CMS explained

that, separate from the dedicated IDL certification criterion, the UDI is a named data element within the USCDI v3 as the “Unique Device Identifier(s) for a patient’s implantable device(s).” CMS noted that UDI is therefore a supported element within the HL7® FHIR® US Core Implementation Guide STU 6.1.0 FHIR IG and Health IT Modules certified to the “standardized API for patient and population services” certification criterion (§ 170.315(g)(10)) must be capable of providing any UDI information available in response to requests for patient data. CMS also identified the standardized API for patient and population services criterion as required to support fulfillment of the measure, which is also part of the Base EHR definition in § 170.102 and thus already incorporated into the CEHRT definition at 42 CFR 495.4. CMS welcomed comments as to whether other certification criteria should be considered to support this measure.

In the 2027 IPPS/LTCH PPS final rule, CMS adopted the Unique Device Identifiers for Implantable Medical Devices measure within the Public Health and Clinical Data Exchange objective as proposed (91 FR 50055). Many commenters supported CMS’s proposal to adopt the measure, noting that recording UDI in EHRs would improve post-market surveillance and care coordination, reduce patient safety risks, and enable faster, more accurate public health responses (91 FR 50057). However, another commenter expressed concern with ONC’s proposal to remove the IDL certification criterion, stating that removal could impact performance on the Unique Device Identifiers for Implantable Medical Devices measure (91 FR 50060).

After consideration of the public comments CMS received, CMS finalized its proposal to adopt the Unique Device Identifiers for Implantable Medical Devices measure beginning with the EHR reporting period in CY 2027 (91 FR 50060). In response to comments regarding potential removal of the IDL certification criterion, CMS stated its belief that health IT functionality related to UDI access, storage, and exchange would continue to be maintained because other certification criteria under the Certification Program continue to reference or support exchange of UDI for implantable devices, including the “standardized API for patient and population services” certification criterion (91 FR 50060). CMS also noted that removal of the specific IDL certification criterion would not preclude health IT developers from continuing to support

Access GUDID lookup, device attribute display, validation, or related functionality. CMS further stated that it would continue to coordinate with ONC and monitor implementation to ensure that hospitals and CAHs have appropriate certified health IT capabilities to support UDI capture and exchange (91 FR 50060).

ONC and CMS are committed to ensuring ongoing support for UDI-related functions. In order to more fully support the new Unique Device Identifiers (UDIs) for Implantable Medical Devices measure within the Public Health and Clinical Data Exchange objective in the Medicare Promoting Interoperability Program, we have not finalized our proposal to remove the IDL certification criterion from the Certification Program. In addition, as noted above, we have not finalized our proposal to remove § 170.315(a)(14) from the Base EHR definition (please see section III.C.1 of this final rule). Therefore, health IT developers will need to continue to certify their health IT to the IDL certification criterion and maintain certification to the IDL certification criterion to meet the Base EHR definition. In addition, eligible hospitals and CAHs attesting to the new Unique Device Identifiers (UDIs) for Implantable Medical Devices measure will continue to have the IDL functionality because, as noted above, the IDL certification criterion is included in the Base EHR definition and thus already incorporated into the CEHRT definition.

Comments. Some commenters noted that finalization of our proposal would require additional guidance or specification of how certified health IT should continue to support functionality such as standardized parsing of UDIs and retrieval of device attributes from GUDID (including SNOMED CT®-encoded information).

Response. Having not finalized our proposal, the IDL certification criterion remains part of the Certification Program and all relevant guidance for compliance with the criterion is still applicable such as the IDL Certification Companion Guide.¹⁹

2. Care Coordination Certification Criteria

a. Transitions of Care

We proposed to revise the “transitions of care” certification criterion in § 170.315(b)(1) to simplify its requirements, with an effective date of January 1, 2027. The transitions of care criterion supports the ability to create,

¹⁹ <https://healthit.gov/test-method/implantable-device-list/>.

send, and receive care summaries and referral summaries to ensure continuity and care coordination as patients move between providers (90 FR 60984). We proposed to reduce the scope of the criterion to focus on enabling the receipt of a Consolidated CDA (C-CDA) document as a way to position this criterion for a future evolution to receipt of FHIR-formatted data. We proposed to remove the requirements in § 170.315(b)(1)(i) “send and receive via edge protocol” and in § 170.315(b)(1)(iii) “create” and to simplify the requirements in § 170.315(b)(1)(ii) “validate and display” to focus on the ability to receive and validate C-CDA documents. We proposed to remove the requirements in § 170.315(b)(1)(ii)(B) and (C). We also proposed to move the requirements in § 170.315(b)(1)(ii)(A) “validate C-CDA conformance—system performance” to § 170.315(b)(1)(i) and to rename § 170.315(b)(1) to read “transitions of care—receive and validate.” Additionally, in § 170.315(b)(1)(ii)(A) we proposed to remove the references to § 170.205(a)(3) and to replace the references to § 170.205(a)(5), which expired on January 1, 2026, with references to § 170.205(a)(6).

Comments. The majority of commenters were not supportive of our proposal to revise the transitions of care certification criterion to remove or narrow C-CDA creation and transmission capabilities for transitions of care/referral summaries, primarily due to concerns about timing and readiness with respect to transitioning to FHIR-based document exchange for transitions of care. Many commenters stated that C-CDA-based document exchange is still widely used, and some stressed that certain settings, including long-term and post-acute care (LTPAC), behavioral health, small, rural and safety net providers, are particularly reliant on C-CDA-based document exchange in current transitions of care workflows. Several commenters expressed concerns that both C-CDA and Direct secure messaging serve as core national exchange mechanisms at this time. Several commenters stated that readiness for FHIR-based exchange is uneven across settings, and thus the proposal could increase disparities. Several commenters stated that C-CDA-based document exchange functions as the current means of sharing structured health information with dental providers, who are less FHIR-ready. Another commenter noted that many public health systems are dependent on C-CDA-based document exchange and

may face data quality or compatibility challenges without a viable alternative. Many commenters stressed that there is currently no mature and broadly adopted FHIR-based replacement for C-CDA-based document exchange and had concerns that without a replacement, removal of C-CDA creation and transmission capabilities would weaken interoperability, increase burden, disrupt care coordination, and increase patient safety risks. Additionally, many commenters expressed concern that there is no phased migration plan, readiness criteria, sunset roadmap, or clear bridge between current C-CDA-based document exchange requirements and future FHIR-based exchange requirements. Several commenters stated that C-CDA-based document exchange remains a necessary backup, and several stated that C-CDA-based document exchange supports migration to FHIR.

Response. We thank commenters for expressing their concerns regarding FHIR readiness and the removal of the current C-CDA-based document exchange requirements in § 170.315(b)(1). We appreciate the concerns expressed by commenters about the impact the proposal would have on C-CDA-based document exchange, which continues to be widely used, particularly in specific settings, as well as the impact on Direct secure messaging. We have reconsidered our proposed policy and have decided to finalize our proposal with modification by extending the timeline for removing the Direct requirements and the C-CDA-based document exchange requirements in § 170.315(b)(1) to January 1, 2030. Specifically, we have finalized our proposed removal of § 170.315(b)(1)(i) “send and receive via edge protocol,” § 170.315(b)(1)(iii) “create,” § 170.315(b)(1)(ii)(B) “display,” and § 170.315(b)(1)(ii)(C) “display section views” with an effective date of January 1, 2030. We have finalized the proposed removal of references to § 170.205(a)(3) in § 170.315(b)(1)(ii) and replacement of references to § 170.205(a)(5) in § 170.315(b)(1)(ii) with references to § 170.205(a)(6) as of the effective date of this final rule. We have not finalized the proposed renaming of the criterion and renumbering of the requirements in § 170.315(b)(1)(ii)(A). We note that in the Proposed Rule we did not propose to remove references to § 170.205(a)(3) or replace references to § 170.205(a)(5) with references to § 170.205(a)(6) in § 170.315(b)(1)(ii)(B) and (C) and in § 170.315(b)(1)(iii) because we proposed to remove § 170.315(b)(1)(ii)(B) and (C) and § 170.315(b)(1)(iii) entirely.

However, because we have not finalized our proposal to remove § 170.315(b)(1)(ii)(B) and (C) and § 170.315(b)(1)(iii) as of the effective date of a final rule, but the references to § 170.205(a)(3) and (5) remain outdated, we have finalized removal of references to § 170.205(a)(3) and replacement of references to § 170.205(a)(5) with references to § 170.205(a)(6) in § 170.315(b)(1)(ii)(B) and (C) and in § 170.315(b)(1)(iii) as of the effective date of this final rule, similar to how we proposed and finalized removal of references to § 170.205(a)(3) and replacement of references to § 170.205(a)(5) with references to § 170.205(a)(6) in § 170.315(b)(1)(ii).

Delaying the effective date of removal of § 170.315(b)(1)(i) “send and receive via edge protocol” and § 170.315(b)(1)(iii) “create” to January 1, 2030, helps address commenter concerns regarding our proposed removal of C-CDA-based standards requirements and Direct secure messaging requirements from the Certification Program. Significant advances are occurring in the development and adoption of FHIR-based standards, and the revised deadline of January 1, 2030, allows for a more gradual and achievable adoption of FHIR-based exchange. In response to concerns regarding C-CDA being considered a necessary backup, we note that while we anticipate that the extended timeline will allow increased adoption of FHIR-based exchange, the removal of C-CDA-based exchange requirements in § 170.315(b)(1) does not prevent the use of C-CDA-based exchange standards where necessary for users. In response to comments expressing concerns regarding the lack of a phased transition plan or roadmap for moving from C-CDA-based exchange to FHIR-based exchange, we note that providing this extended deadline will serve as a helpful timeline and migration pathway for moving from C-CDA-based document exchange to FHIR-based document exchange. Additionally, ONC will continue to provide resources related to transitioning to FHIR-based exchange.

Comments. There were multiple comments about timing challenges, and a number of commenters recommended extending the deadline for removal of C-CDA-based document exchange requirements in § 170.315(b)(1). Several commenters urged ONC to adopt FHIR-based exchange standards for transitions of care prior to removing C-CDA-based document exchange requirements. Another commenter stated that the proposed January 1, 2027, deadline for removing § 170.315(b)(1)(i) would

require new developers to meet the requirements of § 170.315(b)(1)(i) for potentially just a portion of a year before they would need to transition to a FHIR-based exchange alternative. The commenter recommended allowing developers who are actively developing certified health IT to be allowed to meet the new proposed § 170.315(b)(1) requirements rather than fully implement the current § 170.315(b)(1)(i) requirements for a short compliance period.

Response. We thank commenters for expressing their timing concerns, including the January 1, 2027, deadline for removal of C-CDA-based document exchange requirements in the proposed rule and the need for more time for movement away from C-CDA-based document exchange toward FHIR-based exchange. In order to provide more time for transition away from C-CDA based document exchange requirements, we have extended the deadline for removal of § 170.315(b)(1)(i) and (iii) to January 1, 2030. We note that this extension would also address concerns regarding new developers having to meet the current requirements in § 170.315(b)(1)(i) for less than a year before the requirements are revised.

Comments. A number of commenters expressed concerns that the proposal to remove C-CDA-based document exchange requirements could create interoperability gaps and fragmentation. Some commenters expressed concern that developers would implement these functions less consistently, stop supporting them altogether, or charge more for them once certification no longer required them.

Response. We appreciate these concerns from commenters about interoperability gaps and fragmentation as well as the concerns about developers not providing support for C-CDA-based document exchange or charging more for such support. As stated above, we have extended the deadline for removal of certain C-CDA-based requirements in the transitions of care certification criterion in § 170.315(b)(1). This extension will limit the potential for providers to experience extra charges or reduced support from developers for C-CDA-based exchange. Additionally, because the certification criterion in § 170.315(b)(1) is widely adopted, we do not anticipate interoperability gaps as more developers move to FHIR-based exchange, nor do we anticipate that developers would cease supporting functionality for transitions of care after the January 1, 2030, expiration date due to the removal of certain C-CDA-based requirements in the certification criterion.

Comments. A number of commenters expressed concern that the proposal to remove C-CDA-based document exchange requirements would result in increased burden. Some commenters stated that testing, validation, troubleshooting, integration, and governance burdens would move to providers, health information exchange (HIE) or health information network (HIN) operators, public health agencies, or shared service networks. Another commenter stressed that if certification no longer covers create and send capabilities, then implementation consistency may degrade and may increase downstream burden. Some commenters stated that the proposal could result in a return to manual workflows, likely increasing errors, delays, and administrative burden. Some commenters stated that the proposal could result in added fees from developers for C-CDA-related capabilities, unwanted technology changes, or adoption of technology that was not ready.

Response. We thank commenters for expressing these concerns about increased burden and fees. We recognize the importance of ensuring that additional burden is not placed on providers when removing requirements related to C-CDA-based document exchange. As stated previously, we have extended the deadline for removal of certain C-CDA-based requirements in the transitions of care certification criterion in § 170.315(b)(1) to January 1, 2030. This extension provides additional time for more achievable and broader adoption of FHIR-based exchange, and as such we do not anticipate significantly increased burden on providers or added fees for capabilities that are not required by a certification criterion.

Comments. A number of commenters expressed concerns about patient safety risks and impact on care coordination. Some commenters stated the proposed removal of C-CDA-based document exchange requirements could result in various issues related to continuity of care, including missing or delayed clinical context during care handoffs, adverse events, readmissions, and mortality. Some commenters stated that removing transitions of care criterion requirements weaken the Certification Program's role as a national safety and accountability floor. Several commenters stated that the proposal directly threatens patient safety in LTPAC settings and emphasized the high-risk nature of transitions of care.

Response. We appreciate these comments regarding patient safety and care coordination, especially in

particular settings. We understand the importance of making sure that health information is exchanged safely and reliably during transitions of care. We have extended the deadline for the removal of certain C-CDA-based document exchange requirements in the transitions of care certification criterion in § 170.315(b)(1) to January 1, 2030. This extension will allow more time for certified health IT to move away from C-CDA-based standards and for more achievable adoption of FHIR-based exchange. We do not anticipate that this transition would negatively impact interoperability during transitions of care and thus endanger patients or increase safety risks. Also, the certification criterion in § 170.315(b)(1) is widely adopted, and we do not anticipate patient safety risks due to developers ceasing to support this certification criterion functionality after the January 1, 2030, expiration date of certain C-CDA-based document exchange requirements.

Comments. A number of commenters expressed concern about patient matching. Many of these commenters stated that removing “create” requirements in § 170.315(b)(1)(iii) would essentially eliminate the only certification criterion requirement that explicitly relates to patient matching and could thus increase the risk of misidentification and create issues regarding patient safety, privacy, billing, and care coordination.

Response. We thank commenters for sharing these concerns regarding the impact of our proposal on patient matching capabilities in certified health IT. We disagree that § 170.315(b)(1)(iii) is the only certification criterion in the Certification Program that relates to patient matching and that could be used to ensure appropriate support for the data elements needed for effective patient matching. For example, § 170.315(g)(10) requires support for the data elements needed for effective patient matching, including the exchange of USCDI data elements for patient name, date of birth, and address.

Comments. Several commenters expressed concern about the proposed removal of requirements related to Direct and edge protocol, which were described as still necessary for security purposes.

Response. We thank commenters for these comments and appreciate these concerns. We have extended the deadline for the removal of the “send and receive via edge protocol” requirements in the transitions of care certification criterion in § 170.315(b)(1)(i) to January 1, 2030. We anticipate that the extended time for

removal of the requirements will allow for more achievable and broader adoption of secure FHIR-based exchange, which we believe will alleviate concerns about impacts to security.

Comments. Some commenters expressed concerns about alignment with CMS and other Federal or State programs built around C-CDA or Direct workflows with some mentioning State program submission requirements, HIE/HIN enabled exchange, TEFCAs-related exchange, and other Federal program dependencies.

Response. We thank commenters for these comments regarding alignment with Federal and State programs. With respect to the Medicare Promoting Interoperability Program for eligible hospitals and CAHs and the Promoting Interoperability performance category of MIPS, the certification criterion in § 170.315(b)(1) is currently specified as required for the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures and specified as an example of a criterion that may be used to support the actions of the HIE Bi-directional Exchange and Enabling Exchange under TEFCAs measure.

In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19312), CMS proposed to remove the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures beginning with the EHR reporting period in calendar year 2028 (91 FR 19622). In the FY 2027 IPPS/LTCH PPS final rule, which appeared in the **Federal Register** on August 4, 2026, CMS finalized these proposals with modification, finalizing removal of the measures from the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2029 (91 FR 49570). However, our final policy to delay removal of certain requirements in the criterion in § 170.315(b)(1) from the CFR will extend the period during which the currently available set of certified functionality is available to support the actions identified in the measure. We will continue to coordinate with CMS on the finalization of this policy to ensure alignment around the requirements of these measures and certification criteria available in the Certification Program.

We note that, as of the publication date of this final rule, CMS has not proposed to revise or remove the Support Electronic Referral Loops by Sending Health Information and

Support Electronic Referral Loops by Receiving and Reconciling Health Information measures from the Promoting Interoperability performance category of MIPS. With respect to State program requirements, we note that nothing in our finalized policy would prevent a user of certified health IT from following requirements established for State programs or from using HIE/HIN enabled exchange.

Comments. Several commenters stated that the proposal was not the best way to reduce burden and that burden reduction could come from removing duplicative testing elsewhere, especially regarding § 170.315(e)(1), or by changing the testing approach.

Response. We appreciate these comments regarding reducing burden by removing duplicative testing elsewhere. In section III.A.5.a of this final rule we discuss proposed revisions to § 170.315(e)(1), and we note that while we revised the criterion, we did not propose removal for burden reduction purposes. However, in section III.A.7.f of this final rule, we have finalized our proposal to remove the certification criterion in § 170.315(g)(6) for burden reduction purposes. This reduces burden because § 170.315(g)(6) is a conditional, secondary C-CDA implementation requirement that is applied to health IT for which certification to a primary C-CDA-based certification criterion is sought and would require duplicative testing to the ability to generate and format C-CDA files.

Comments. Several commenters expressed support for the proposal. These commenters stated that the proposal reduced burden and was consistent with a FHIR-forward, deregulatory approach. Some commenters stated that the criterion was duplicative and added complexity without benefit. Several commenters noted that the testing tool was not user-friendly.

Response. We thank commenters for expressing their support for this proposal. We agree with commenter assessments that the proposal will reduce burden and encourage movement toward FHIR-based exchange. We have finalized the proposal with modifications. We have extended the effective date of our proposed revisions to § 170.315(b)(1) to January 1, 2030, with the exception of the removal of references to § 170.205(a)(3) and replacement of references to § 170.205(a)(5) with references to § 170.205(a)(6), which we have finalized as of the effective date of a final rule. We have not finalized the proposed renaming of the criterion and

renumbering of the requirements in § 170.315(b)(1)(ii)(A).

Comments. Several commenters identified issues that were out of scope for our proposal, such as broader patient-matching legislation or standards, proposals to strengthen the criterion, support for Qualified Health Information Network (QHIN) participation, a proposal for new certification requirements to create a FHIR-based summary of care for transitions of care, and proposals for future recognition of additional specialty-specific FHIR implementation guides.

Response. We thank commenters for these comments. However, these comments were outside the scope of this rulemaking.

b. Clinical Information Reconciliation and Incorporation

We proposed to remove the “clinical information reconciliation and incorporation” certification criterion in § 170.315(b)(2) with an effective date of January 1, 2027, and to reserve that section. The clinical information reconciliation and incorporation (CIRI) certification criterion allows health care providers to reconcile and incorporate patient health information in C-CDA format sent from external sources to maintain a more accurate and up-to-date patient record. The CIRI certification criterion is not currently included in the Base EHR definition. However, the criterion is required in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure and also is specified as an example of a criterion that may be used to support the actions of the HIE Bi-Directional Exchange and Enabling Exchange under TEFCAs measures in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.²⁰

Comments. The majority of commenters were not supportive of removing the CIRI certification criterion in § 170.315(b)(2), generally due to concerns about timing and FHIR readiness. Commenters expressed concern that FHIR-based alternatives are not yet mature, adopted, or available across all care settings. Several commenters stated that existing C-CDA-based document exchange remains foundational and often the only

²⁰ See the CY 2026 PFS Proposed Rule Table 62, available at <https://www.federalregister.gov/d/2025-13271/p-3055> and the FY2026 IPPS/LTCH PPS Final Rule Table X.F.–05 available at <https://www.federalregister.gov/d/2025-14681/p-4161>.

mechanism available in many settings. Another commenter stated that EHRs must be able to generate and transmit C–CDA documents in order for many receiving systems to incorporate any data at all. Several commenters stated that small, rural, safety-net, behavioral health, LTPAC, and other settings with limited resources are less ready and able to move to FHIR-based standards and could thus face wider disparities. Some commenters expressed concern about the lack of a phased plan or roadmap for transitioning to FHIR-based standards, and some commenters urged timeline extensions for transition. There were also several comments that removal of the criterion prior to a FHIR-based replacement being widely available would create a regulatory gap, and commenters expressed concern that external data may remain siloed, duplicative, incomplete, or inaccurately incorporated. Additionally, commenters expressed concern that a gap due to lack of a FHIR-based replacement would weaken baseline safety and interoperability protections, increase manual reconciliation burden, shift administrative burden to clinicians and providers that still rely on existing exchange workflows, and create risks for care coordination, transitions of care, and patient safety. Several commenters recommended ONC delay removal or adopt a phased transition to FHIR-based exchange instead, and another commenter recommended that ONC retain the CIRI certification criterion in § 170.315(b)(2) as a functional requirement, thus allowing developers more flexibility in adopting FHIR-based solutions.

Response. We appreciate these concerns regarding FHIR readiness and removal of the current C–CDA-based document exchange requirements in § 170.315(b)(2) prior to a mature and widely adopted FHIR-based alternative being in place. Additionally, we understand that C–CDA-based document exchange is currently widely used, particularly in certain settings. Further, we appreciate the concerns expressed by commenters that due to a perceived lack of mature and widely adopted FHIR-based replacements, removal of the criterion in § 170.315(b)(2) could increase manual reconciliation burden and shift administrative burden to clinicians and providers. We also appreciate the recommendation to consider retaining the certification criterion in § 170.315(b)(2) as a functional requirement and agree that would provide developers of certified health IT

more flexibility to adopt FHIR-based solutions.

We have reconsidered our proposed policy and have not finalized complete removal of the certification criterion in § 170.315(b)(2). Instead, we have reduced the burden for certification to this criterion and increased flexibility for certification. First, we have provided that health IT can demonstrate conformance with the criterion in a broader range of workflows instead of only upon receipt of a transition of care/referral summary. For example, health IT could demonstrate the ability to reconcile information according to the certification criterion's requirements when received from a patient, during internal patient transitions within a health care system, or when a patient is discharged to any external entity. Second, we have finalized removal of the references to standards for exchanging electronic health information in § 170.315(b)(2), thus making it a functional criterion, effective with the effective date of this final rule. Last, we have finalized the removal of the requirement to simultaneously display the data from at least two sources in a manner that allows a user to view the data and their attributes. We believe this finalized policy will not result in provider burden from manual reconciliation or provider burden from increased cost for electronic reconciliation functions, and at the same time will allow movement toward innovative, FHIR-based solutions. Additionally, as noted in the Proposed Rule (90 FR 60984) and discussed in more detail in a comment response below, the criterion in § 170.315(b)(2) is required for certain CMS measures, and maintaining it as a functional criterion ensures that certified functionality is available to support the actions identified in those measures.

We have finalized removal throughout § 170.315(b)(2) of the requirements to use the content exchange standards and implementation specifications specified in § 170.205(a)(3), (4), and (6) for exchanging electronic health information, as well as made conforming revisions for clarity and readability related to the removal of references to those standards. As noted above, we have also finalized removal of references to the standard in § 170.205(a)(5) which expired on January 1, 2026. In addition, we have finalized removal of the requirement to simultaneously display (*i.e.*, in a single view) information received from another source. We believe removal of this requirement is consistent with our objective of providing greater flexibility

under the criterion while reducing unnecessary burden. We understand that the simultaneous display requirement may, in some cases, have constrained the development and implementation of improved workflows. We are also aware that some health IT developers are pursuing more automated approaches to reconciliation, including approaches for data received from trusted sources. Accordingly, we expect removal of this requirement will afford health IT developers greater flexibility to design and implement more efficient and innovative reconciliation workflows that better support clinician users, including automated approaches to reconciliation. As finalized, the criterion requires the ability to match data received from a transition of care/referral summary or other workflow with the correct patient; create a single reconciled list of medications, allergies and intolerances, and problems; enable user review and validation of the accuracy of a final set of data; and upon a user's confirmation, automatically update the list and incorporate medications, allergies and intolerances, and problems expressed according to, at a minimum, the version of the standard in § 170.213. We note that we do not expect that a health IT developer with a Health IT Module currently certified to § 170.315(b)(2) would need to make any changes to the certified Health IT Module to meet the revised criterion, because if a health IT developer's Health IT Module was previously conformant to the certification criterion in § 170.315(b)(2), then the Health IT Module would also be conformant to the revised criterion. Since we have not removed this certification criterion in its entirety, we have made the revisions effective with the effective date of this final rule. This will provide health IT developers with the discussed flexibility and reduced burden as soon as practical.

Comments. Many commenters expressed concerns about patient safety. A number of commenters had concerns that removal of the certification criterion in § 170.315(b)(2) could compromise patient safety during transitions of care and medication reconciliation. Several commenters stated that removal of the certification criterion would weaken care coordination, continuity of care, referrals, and integrated or team-based care. Multiple commenters stated that certification was like a national safety floor or baseline safeguard and removing the criterion would reduce accountability, transparency, uniformity, and assurance that

important capabilities remain available, ultimately impacting patient safety. Another commenter stated that removing the certification criterion could reduce motivation to provide or use reconciliation functionality uniformly, which could affect accurate quality reporting.

Response. We appreciate commenter concerns regarding patient safety, and we understand the importance of ensuring that health information is exchanged reliably during transitions of care and reconciliation. We have not finalized complete removal of the certification criterion in § 170.315(b)(2) as proposed and instead have finalized removal of the requirements in § 170.315(b)(2) to use the content exchange standards and implementation specifications in § 170.205(a)(3), (4), and (6) for exchanging electronic health information, thus making it a functional criterion. We believe this addresses concerns from commenters by ensuring that certified health IT has the capability of reconciling and incorporating patient health information appropriately.

Comments. There were a number of comments related to burden. Many commenters stated that the proposal would increase manual reconciliation, transcription, and workflow burden on clinicians and staff. A commenter stressed that when certified health IT lacks reliable reconciliation functionality, reconciliation burden is shifted directly onto physicians and clinical staff, increasing manual work, workflow inefficiencies, and the risk of incomplete or inaccurate records. Another commenter stated that removing the certification criterion in § 170.315(b)(2) would remove the expectation that reconciliation is supported and increase reliance on manual transcription, significantly raising the risk of errors. Some commenters stated that removal of the certification criterion would shift verification, compliance, operational burden, and in some cases liability from developers or government to providers, and some stressed that this would especially impact small, independent, and rural practices that rely on certified systems to meet regulatory, reporting, and security obligations.

Response. We thank commenters for expressing their concerns that removal of the certification criterion in § 170.315(b)(2) would shift burden to providers. We appreciate the importance of not increasing burden on providers or introducing manual workflows. We have not finalized complete removal of the certification criterion in § 170.315(b)(2) as proposed

and instead have finalized removal of the requirements in § 170.315(b)(2) to use content exchange standards and implementation specifications for exchanging electronic health information, thus making it a functional criterion. We believe this addresses these burden-related concerns from commenters by ensuring that certified health IT has the capability to reconcile and incorporate patient health information electronically.

Comment. There were several comments about timing, and commenters generally stated that the proposed timing was too aggressive, allowed insufficient time to transition to FHIR-based standards, and provided a poorly defined path from current C-CDA-based requirements.

Response. We appreciate concerns regarding the timeline of the proposal and the need for additional time to transition to FHIR-based solutions. We have not finalized removal of the certification criterion in § 170.315(b)(2) as proposed and instead have finalized removal of the requirements in § 170.315(b)(2) to use content exchange standards and implementation specifications for exchanging electronic health information, thus making it a functional criterion. We believe this in effect provides additional time for the transition to FHIR-based solutions while at the same time ensuring that certified health IT maintains the capability to appropriately reconcile and incorporate patient health information electronically.

Comments. Several commenters expressed concerns about aligning with CMS. Another commenter stated that the current proposed timelines would not give CMS time to determine if Promoting Interoperability measures require changes and, if changes are required, it would be impossible for health IT developers to have the changes in place by the start of the 2027 Promoting Interoperability reporting performance year, resulting in significant additional burden for hospitals and providers participating in these programs.

Response. We thank commenters for these comments regarding alignment with CMS. Currently, the certification criterion in § 170.315(b)(2) is required by CMS for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure and specified as an example of a criterion that may be used to support the actions of the HIE Bi-Directional Exchange and Enabling Exchange under TEFCA measures in the Medicare Promoting Interoperability Program (see 86 FR 45490 and 87 FR 49330–49331,

respectively) and the MIPS Promoting Interoperability performance category (see 85 FR 84889 and 87 FR 70084, respectively). We have not finalized removal of the certification criterion in § 170.315(b)(2) as proposed and instead have finalized revisions to § 170.315(b)(2) to make it a functional criterion, thus ensuring that certified functionality is available to support the actions identified in the CMS measures noted above. Therefore, we do not anticipate that our finalized policy will require any changes to the references to this certification criterion in either the Medicare Promoting Interoperability or MIPS programs.

Comments. There were several comments rejecting the “widespread adoption” rationale for removing a certification criterion. Commenters stated that adoption results from certification is not uniform across settings and may not persist after deregulation. Another commenter stated that ONC has not provided data demonstrating that these capabilities are uniformly implemented across all practice sizes, specialties, and healthcare settings and that “widespread” among large health systems is not the same as “widespread” among small practices, rural clinics, behavioral health providers, or SI health applications. Several commenters stated that market incentives do not guarantee continued support and that functionality could become an add-on, be left unmaintained, or be sunset. Another commenter stated that removing certification does not create incentives for improvement but instead risks stagnation.

Response. We thank commenters for these comments regarding our rationale for proposing removal of certification criteria that have been widely adopted. In the Proposed Rule, we explained how we determined which certification criteria could be considered “widely adopted” (90 FR 60979 through 60980). We also referenced recent Real World Testing results regarding routine use of the certification criterion in § 170.315(b)(2) that demonstrate its widespread implementation and use in certified health IT at this time and indicate that the functionality is not likely to be removed (90 FR 60985). While we maintain that the current broad adoption and use of CIRI capabilities would ensure retention of that functionality in certified health IT, we have not, as discussed in detail above, finalized removal of the certification criterion in § 170.315(b)(2) as proposed. This action provides further assurance that this functionality

will be maintained in certified health IT.

Comments. Some commenters expressed support for removal or simplification of the certification criterion in § 170.315(b)(2), stating that it is widely adopted, overly prescriptive, and could permit more flexible and innovative approaches.

Response. We thank commenters for their support of our proposal. We agree with commenters that removal of the criterion in § 170.315(b)(2) would provide room for innovation in this space. However, the finalized functional requirement in § 170.315(b)(2) also will give health IT developers greater flexibility to adopt FHIR-based solutions and innovative approaches, while at the same time ensuring that certified health IT maintains the capability to appropriately reconcile and incorporate patient health information electronically.

Comments. Several commenters expressed concerns that the certification criterion does not address automated or computational reconciliation or define guardrails for SI-assisted reconciliation, human review, auditability, and accountability.

Response. We thank commenters for these comments. While automated, computational, or SI-assisted reconciliation could be workflows and technology used to now meet the requirements of this certification criterion, we did not propose to make them functionalities required to meet the criterion. We also did not propose any form of “guardrails” (e.g., human review or auditability) for inclusion in the CIRI certification criterion. Therefore, these recommendations are generally outside the scope of this rulemaking, and we decline to adopt them in this final rule.

c. Security Tags—Summary of Care

We proposed to remove the “security tags—summary of care—send” certification criterion in § 170.315(b)(7) and the “security tags—summary of care—receive” certification criterion in § 170.315(b)(8) and reserve those sections. Together, these certification criteria are designed to support the application and persistence of security labels for document-based exchange. The security tags—summary of care—send certification criterion in § 170.315(b)(7) enables a user to create a summary record that is tagged as restricted and subject to restrictions on re-disclosure, while the security tags—summary of care—receive certification criterion in § 170.315(b)(8) enables a user to receive a summary record that is tagged as restricted and subject to

restrictions on re-disclosure. These criteria are not currently included in the Base EHR or CEHRT definitions. We proposed to remove the security tags—summary of care—send certification criterion in § 170.315(b)(7) and the security tags—summary of care—receive certification criterion in § 170.315(b)(8) as of the effective date of this final rule.

Comments. The majority of commenters were not supportive of removing the security tags—summary of care—send certification criterion in § 170.315(b)(7) and the security tags—summary of care—receive certification criterion in § 170.315(b)(8), primarily due to concerns that C-CDA-based standards are still widely used at this time and FHIR-based standards are not sufficiently mature or widely adopted. Commenters were concerned that there was not an adequate replacement in place, and many opposed removal of the certification criteria without a transition plan, clear alternative pathway, or FHIR-based replacement. Commenters expressed concerns that removal of the criteria without an adequate replacement would weaken privacy protections for sensitive data, increase variability in implementation, and create risks of over-sharing, under-sharing, or manual workarounds during exchange and transitions of care. A commenter stated that readiness to transition to FHIR is uneven across care settings and that removal without sufficient transition time could increase interoperability gaps, reduce transparency into whether certified technology works reliably across settings, and worsen disparities. Some commenters noted that certain settings have resource limitations and would benefit from retaining the criteria or delaying removal. Several commenters stressed that current C-CDA-based exchange still has meaningful utility and value during the transition to FHIR-based approaches. Some commenters recommended changing certification to attestation or keeping the criteria optional while more progress is made on FHIR standards, and some recommended retaining the criteria or extending timelines for removal. Several commenters recommended a transition plan to minimize disruption and ensure that segmentation capabilities are not lost and that consent and restricted data indicators continue to function consistently across networks.

Response. We appreciate the concerns raised regarding the removal of the C-CDA-based security tags criteria in § 170.315(b)(7) and (b)(8). We recognize that C-CDA-based standards are frequently used for health information exchange at this time; however, as we

stated in the Proposed Rule, there has been limited certification to the security tags criteria in § 170.315(b)(7) and (8) (90 FR 60985). We believe this indicates that the criteria are not as beneficial as some commenters suggest, thus lacking sufficient value as part of the Certification Program, and that there is promising movement toward FHIR-based solutions in the industry (90 FR 60985). We have heard repeatedly that the criteria present implementation challenges and are not effective in managing complex sensitive data. We appreciate that technical solutions to issues around patient consent and data segmentation are notoriously challenging and that current technology does not allow for segmenting specific health data and controlling its disclosure in a way that matches most expectations. Removal of these under-adopted certification criteria from the Certification Program will allow for greater focus on the continued development of a robust and effective FHIR-enabled data privacy and segmentation standard. We believe this focus can lead to more innovation in this area and enable us to propose more effective solutions in the future. Finally, we note that where users are successfully implementing C-CDA based data tagging solutions, including those that have been certified, our removal of the voluntary criteria from the Certification Program does not necessitate removal of such functionality from implemented systems or real world use. We are simply no longer certifying such technology by any means, including through attestation,²¹ as we believe the burden on the Certification Program and health IT developers to be greater than the benefit derived specifically from certification to these criteria. Accordingly, we have finalized removal of the criteria as proposed.

We reassure commenters that we support and encourage technical approaches that offer patients a range of consent choices,²² as we have noted in

²² We note that for purposes of this discussion, when we discuss “consent” and technical approaches to the electronic capture, management, and exchange of patient consent preferences or information in accordance with those preferences, we are addressing technical capabilities, controls, and engineering that may support permissions required under a range of applicable laws, including HIPAA authorizations, consents required under 42 CFR part 2, or State law, and other individual, patient-facing or patient-directed privacy choices, restrictions, or preferences about the disclosure, release, and/or sharing of their information under applicable law. Additionally, for purposes of this discussion, “computable consent” refers to automated, standards-driven, consent capture, management, and exchange, including both

prior rulemaking exploring both the C-CDA and the FHIR Data Segmentation for Privacy (DS4P) standards and related security label taxonomy (See for example 89 FR 1299 through 1305). We intend to maintain our focus on this area in future rulemaking as well as in our work with standards development organizations and health IT innovators. For example, ONC's Leading Edge Acceleration Projects (LEAP) in Health IT program has supported efforts around scalable consent frameworks for the advancement of interoperability with FHIR-based APIs.²³ With respect to comments regarding a transition plan or alternative pathway, we note that the C-CDA exchange requirement in § 170.315(b)(1) would remain in effect until January 1, 2030, providing a clear transition period for developers to support continued use of the security tag capabilities where implemented by users for C-CDA document exchange. We reiterate that the removal of the certification criteria does not necessitate removal of the functionality from health IT systems for users who may have these functions implemented, nor does it prohibit continued use of the referenced standards in existing and new health IT implementations.

Comments. A number of commenters noted that the security tags criteria in § 170.315(b)(7) and (8) are the only existing mechanism in the Certification Program to support the segmentation of sensitive health information and had concerns about removal. Several commenters stressed that the criteria are still needed to protect especially sensitive categories of information, including behavioral health, substance use disorder, and adolescent data, and that removal could limit participation in health information exchange. Some commenters expressed concerns that removing the criteria would lower the security floor for health IT and create more variability in whether and how segmentation tags and security tags are implemented. Several commenters stated that removal of the criteria could increase the risk of over-sharing, under-sharing, or unauthorized sharing of data, especially during referrals and transitions of care. Another commenter stated that removal could encourage under-documentation or make records less reliable if providers avoid documenting sensitive information or rely on nonstandard workarounds.

system-side consent automation and patient-facing request capabilities.

²³ See <https://healthit.gov/interoperability/investments/leap/2019-leap-health-it-projects/> and <https://healthit.gov/blog/onc-funding/san-diego-health-connect-takes-a-big-leap-over-the-barrier-of-consent-management/>.

Response. We appreciate concerns that the security tags criteria in § 170.315(b)(7) and (8) are the only criteria in the Certification Program that support data segmentation and the protection of sensitive health information. As stated above, we support and encourage technical approaches that allow for the electronic capture, management, and exchange of an individual's consent preferences and offer patients a range of choices related to the use and sharing of health information under applicable law. We also note promising industry initiatives in this area, including an increasing availability of consent management tools on the market as well as State and HIE/HIN efforts to advance consent management approaches.²⁴

Comments. Several commenters expressed concern that patients may disengage from or lose trust in health information exchange if computable privacy controls are unavailable. Some commenters expressed concern that removal of the criteria could erode public trust. Some commenters expressed concern that patients with sensitive health information may be harmed or avoid care if the criteria are removed.

Response. We thank commenters for expressing these concerns and understand how critical it is to ensure patient trust in the electronic exchange of health information. As noted above, we support initiatives exploring the capture, management, and exchange of patient consent preferences. Additionally, we note that as described in detail in section III.A.4 of this final rule, we have retained the privacy and security certification criteria in § 170.315(d) and the associated Privacy and Security Certification Framework under § 170.550(h) that we had proposed to remove in the Proposed Rule. We appreciate the concern that patients may disengage or lose trust in health information exchange if computable privacy controls are unavailable. Research indicates that public expectations and preferences for what "computable privacy controls" should deliver are growing,²⁵ and we

²⁴ See for example the CRISP Consent Tool at <https://www.crisphealth.org/consent-tool/>, Washington's Consent Link project at <https://www.hca.wa.gov/about-hca/programs-and-initiatives/clinical-collaboration-and-initiatives/electronic-consent-management>, and the Shift Sandbox at <https://www.shiftinterop.org/our-work/the-shift-sandbox/>.

²⁵ Kassam I, Ilkina D, Kemp J, Roble H, Carter-Langford A, Shen N. (2023). Patient Perspectives and Preferences for Consent in the Digital Health Context: State-of-the-art Literature Review. *Journal of Medical Internet Research*, 25, Article e42507. <https://doi.org/10.2196/42507>.

believe that neither § 170.315(b)(7) nor § 170.315(b)(8) are optimal approaches to meeting those expectations. As document-based approaches tied to summary record exchange, these criteria are not aligned with granular controls pertaining to the release of information, as an individual would expect from modern API-based interactions. Again, we note that removal from the program does not necessitate removal from systems where the standards and functionality have been successfully implemented. Based on input from clinicians and health IT developers, we do understand that some such implementations exist although they are not widely in use. We believe that ongoing development in FHIR can better meet growing public expectations.

Comments. Several commenters stated that developers may deprioritize segmentation capabilities or create proprietary, non-interoperable segmentation and consent solutions if the certification expectation is reduced or removed.

Response. We appreciate these concerns regarding potential actions of developers to deprioritize segmentation capabilities due to removal of the security tags criteria in § 170.315(b)(7) and (8). However, as previously noted, these criteria are not included in the Base EHR or CEHRT definitions, and have not been required to meet any measures under the Medicare Promoting Interoperability Program or the Promoting Interoperability performance category of MIPS. The inclusion of these criteria in the Certification Program has not driven uptake within the industry, in large part because prioritization of these functionalities that are generally held to be only partially effective would divert resources from other efforts that may have greater efficacy. We understand the importance of ensuring the appropriate capture, management, and exchange of patient consent preferences. As described above, we believe that removal of the certification criteria in § 170.315(b)(7) and (8) will allow more space for innovation in this area, and we intend to maintain a focus on supporting and encouraging technical approaches that offer patients a range of consent choices, including in future rulemaking.

Comments. A number of commenters expressed concerns about burden and warned that removing this functionality without a mature replacement would shift burden to providers. Some commenters stated that removal of the criteria could result in manual redactions based on patient preference, separate documentation, manual

collation, and other workarounds that would shift work to providers and staff.

Response. We appreciate these comments regarding burden shifting due to removal of the security tags criteria in § 170.315(b)(7) and (8) and we understand the importance of not increasing burden on providers. We reiterate that we have heard repeatedly that the criteria present implementation challenges, are not meeting expectations, and are not effective in managing the sharing and/or release of complex sensitive data. Additionally, we note that certification to the criteria is voluntary, and as mentioned in the Proposed Rule and above, few Health IT Modules are currently certified to the criteria (90 FR 60985). Therefore, due to the small number of products certified to these criteria and low implementation, we do not expect that removal of these criteria will result in a significant burden shift to providers. We believe that removal of the security tags criteria in § 170.315(b)(7) and (8) will allow health IT developers and others in industry to move toward more effective technical solutions in this space, and we will continue to support and encourage technical approaches that enable operationalizing patient choices, including through future rulemaking.

Comments. Several commenters rejected “low uptake” as a sufficient reason for removal, arguing that the underlying privacy need remains. Another commenter stated that low adoption is not a valid reason to remove protections when an underlying need persists.

Response. We thank commenters for these comments regarding the low level of certification to the security tags criteria in § 170.315(b)(7) and (8). As stated above, we believe the relatively small number of products certified to these criteria indicates that they do not have sufficient value to the users or implementers. In addition to the low level of certification, we have received multiple complaints that the criteria present implementation challenges and can be ineffective, which also influenced our proposal to remove these criteria. For example, industry has reported that security labels required by § 170.315(b)(7) and (8) can be difficult to use consistently because different systems may label, interpret, and enforce sensitive information differently, which limits how reliably those labels protect data when information is exchanged between organizations.²⁶ We agree with

commenters that privacy needs are important to address. We believe that removal of the security tags criteria in § 170.315(b)(7) and (8) will allow health IT developers and industry to develop and adopt more effective solutions in this space, and we will continue to focus on identifying and supporting technical approaches that enable a range of consent choices.

Comments. A commenter stated that maintaining these voluntary criteria would not add burden but would continue to signal the importance of a standards-based approach to computable consent.

Response. We thank the commenter for this comment, and we agree that standards-based approaches to computable consent are very important. As stated above, ONC supports initiatives working to improve the capture, management, and exchange of patient consent preferences, and we note promising growth in industry initiatives in this area and an increasing availability of consent management tools. We support and encourage technical solutions that enable computable consent, and we intend to maintain a focus on this issue in future rulemaking.

Comments. A commenter had concerns about alignment with CMS and recommended delaying removal of these criteria until at least 2028 so that ONC can work with CMS to ensure alignment between its program requirements and evolving ONC certification criteria.

Response. We thank the commenter for this comment. We note that currently there are no CMS requirements requiring health care providers to adopt or use health IT certified to the certification criteria in § 170.315(b)(7) and (8). We do not believe that removal of these criteria will lead to regulatory alignment concerns for health care providers participating in CMS programs. Additionally, we note that the criteria are not included in the definition for Base EHR at 45 CFR 170.102.

Comments. Some commenters expressed support for removal, noting that the criteria have had low adoption and limited real-world utility.

Response. We thank commenters for these comments in support of our proposal to remove the security tags criteria in § 170.315(b)(7) and (8). We agree with commenters that the criteria have been poorly adopted and have limited utility. We have repeatedly

heard complaints that the criteria present implementation challenges and can be ineffective. We have finalized the proposal to remove the security tags criteria in § 170.315(b)(7) and (8) as of the effective date of a final rule.

d. Care Plan

We proposed to remove the “care plan” certification criterion in § 170.315(b)(9) and reserve that section as of the effective date of a final rule. The certification criterion in § 170.315(b)(9) helps improve coordination of care by providing a structured format for documenting patient information such as goals, health concerns, health status evaluations, and interventions. The criterion is not currently included in the Base EHR definition.

As of September 2026, 48 unique Health IT Modules are certified to the criterion in § 170.315(b)(9) out of a total of 714 active and non-suspended certifications listed on the Certified Health IT Product List (CHPL),²⁷ indicating low interest by health IT developers in certifying to this criterion. We also noted in the Proposed Rule that the industry is moving away from C–CDA-based standards to the use of FHIR-based standards, and we highlighted the development of FHIR-based care plan implementation guides (IGs), including the Multiple Chronic Condition eCare Plan and the Electronic Long Term Services & Support Care Plan IGs (90 FR 60986). Additionally, we noted input from industry that the care plan document type is less frequently adopted than other C–CDA document types, and where it is utilized, health IT developers are not likely to cease supporting the functionality if the criterion is removed from the Certification Program (90 FR 60986).

Comments. The proposal received relatively few comments, and the majority of commenters were not supportive of removing the care plan certification criterion in § 170.315(b)(9), primarily due to concerns that FHIR adoption and readiness were uneven and immature and there was not a viable replacement standard or plan for transitioning to FHIR. Commenters noted a lack of widespread use of FHIR push capabilities, interoperability issues with legacy systems, uneven adoption of FHIR across organizations, maintenance burdens, and inconsistent use of terminologies and value sets as examples of FHIR challenges and readiness issues. Commenters expressed

²⁶ Sarabu C, Sharko M, Petersen C, Galvin H. (2023). Shifting into Action: from Data Segmentation to Equitable Interoperability for

Adolescents (and Everyone Else). *Applied Clinical Informatics*, 14(3), 544–554. <https://doi.org/10.1055/s-0043-1769924>.

²⁷ <https://chpl.healthit.gov> search conducted September 2026.

concerns that removing a criterion that relies on C-CDA-based standards at a time when FHIR-based standards are not mature and widely adopted would weaken care coordination, increase patient safety risks, and exacerbate interoperability gaps during the transition from C-CDA-based exchange to FHIR-based exchange. Several commenters cautioned that removing this requirement prematurely could increase administrative burden, create fragmentation across care settings, and disproportionately affect rural, small, safety net, dental, and other providers that continue to rely on existing C-CDA-based document exchange. Several commenters stressed that some settings were less ready to transition to FHIR, such as LTPAC, behavioral health, small, rural, safety-net, and dental settings, and that removal of the criterion could widen interoperability gaps and disparities.

Response. We thank commenters for expressing these concerns regarding the removal of the care plan certification criterion in § 170.315(b)(9). We appreciate the points expressed by commenters that FHIR-based alternatives are not mature and widely available at this time and that certain settings are not ready to transition to FHIR. However, we note that the care plan certification criterion in § 170.315(b)(9) is just one of several certification criteria in the Certification Program that require use of C-CDA-based document exchange standards. The transitions of care certification criterion in § 170.315(b)(1) includes C-CDA-based requirements, and as discussed earlier in section III.A.2.a, we have extended the timeline for removing the C-CDA-based creation and transmission requirements in § 170.315(b)(1) until January 1, 2030. Also, we are retaining the requirements in § 170.315(b)(1)(ii)(A) to validate C-CDA performance beyond January 1, 2030. We believe this addresses commenter concerns regarding the removal of C-CDA-based requirements from the Certification Program. Further, as we noted in the Proposed Rule, adoption of the certification criterion in § 170.315(b)(9) is currently very low and removal of the certification criterion would help promote greater innovation and advancement in this area (90 FR 60986). Given these factors, we have finalized the removal of the criterion in § 170.315(b)(9) as of the effective date of this final rule as proposed.

Comments. Several commenters expressed concerns about patient safety and stated that removal of the criterion could result in incomplete, delayed, lost, duplicated, or insufficiently

supported health information. Several commenters stated that the criterion was still viewed as providing baseline safeguards and that removal could lead to degradation, inconsistency, loss of capability, or less transparency about whether certified tools perform reliably.

Response. We appreciate commenter concerns about patient safety, and we understand the importance of ensuring that health information is exchanged reliably as part of patient care and care coordination. As stated above, we note that the care plan certification criterion in § 170.315(b)(9) is not the only certification criterion in the Certification Program that requires use of C-CDA-based standards and helps ensure reliable exchange of clinical data for patient care. The transitions of care certification criterion in § 170.315(b)(1) includes C-CDA-based requirements, and as discussed earlier in section III.A.2.a, we have extended the timeline for removing the C-CDA-based creation and transmission requirements in § 170.315(b)(1) until January 1, 2030. This extension should provide time for certified health IT to move from C-CDA-based standards to FHIR-based standards for exchange without sacrificing patient safety and help address commenter concerns. Also, we are retaining the requirements in § 170.315(b)(1)(ii)(A) to validate C-CDA performance beyond January 1, 2030. We do not believe it is necessary to also maintain requirements in § 170.315(b)(9) because health IT developers are likely to continue supporting C-CDA-based exchange under § 170.315(b)(1), which also contains requirements to support C-CDA document templates. Additionally, as we stated in the Proposed Rule, we do not believe that health IT developers are likely to cease supporting the functionality in § 170.315(b)(9) if the criterion is removed from the Certification Program (90 FR 60986). We also note that USCDI v3 includes data elements supporting the exchange of the components of a care plan, including Problems, Clinical Tests, Procedures, and Patient Goals. Additionally, USCDI v6 adds a Care Plan data element, and the USCDI standard follows the Standards Version Advancement Process (SVAP) to allow health IT developers to update their systems to newer version of USCDI and provide these updates to their customers.²⁸ We note that beginning August 29, 2026, health IT developers participating in the Certification Program may voluntarily use the 2026 SVAP-approved standards,

which include USCDI v6, in their certified Health IT Modules.²⁹

Comments. Several commenters stated that removal of the certification criterion in § 170.315(b)(9) without ensuring support for the functionality while transitioning to FHIR could shift burden to providers, clinicians, and system administrators. Commenters stated that this could result in manual workflows, manual transcription, and added operational burden, especially for smaller or under-resourced practices.

Response. We thank commenters for expressing these concerns about burden and appreciate the importance of not imposing additional burden on providers. As stated above, we have extended the deadline for removal of C-CDA-based creation and transmission requirements in the transitions of care certification criterion in § 170.315(b)(1), and this extension will provide time for certified health IT to move from C-CDA-based standards to FHIR-based standards without significantly increasing burden on providers. We do not believe it is necessary to also maintain requirements in § 170.315(b)(9) because health IT developers are likely to continue supporting C-CDA-based exchange under § 170.315(b)(1). Further, as discussed above we do not believe that health IT developers that currently support this functionality are likely to cease supporting the functionality in § 170.315(b)(9) if the criterion is removed from the Certification Program, and therefore we do not anticipate additional burden on providers associated with removal of the criterion or a shifting of burden to providers.

Comments. Several commenters disagreed that vendors would voluntarily keep the same functionality after deregulation and stated that vendors may stop maintaining the functionality, let the functionality become obsolete, or charge extra for the functionality. Another commenter stressed that the care plan criterion was one of the few certification signals to developers that care planning matters and recommend that ONC identify alternative pathways to accelerate adoption of care planning functionality.

Response. We appreciate these concerns from commenters regarding developers ceasing to support C-CDA-based exchange and care plan documents or charging more for the functionality. We understand the importance of ensuring that support for C-CDA-based exchange and Care Plan

²⁸ See <https://isp.healthit.gov/united-states-core-data-interoperability-uscdi#uscdi-v6>.

²⁹ See <https://healthit.gov/blog/standards/advancements-in-health-it-oncs-2026-approved-svap-standards/>.

functionality is continued during a transition to FHIR-based exchange. However, because this functionality is so widely adopted, we are not persuaded that developers will cease supporting C-CDA-based exchange and care plan documents, or charge more for such functionality, due to removal of the criterion in § 170.315(b)(9). As stated above, other certification criteria in the Certification Program also require use of C-CDA-based standards, including the transitions of care certification criterion in § 170.315(b)(1), and can help ensure support of C-CDA-based standards during a transition from C-CDA-based exchange to FHIR-based exchange. We have extended the deadline for removal of C-CDA-based creation and transmission requirements in the transitions of care certification criterion in § 170.315(b)(1) to January 1, 2030. We do not believe it is necessary to also maintain requirements in § 170.315(b)(9) because health IT developers are likely to continue supporting C-CDA-based exchange under § 170.315(b)(1). Regarding alternative means of encouraging care planning functionality, we note that USCDI v3 includes data elements supporting the exchange of the components of a care plan, including Problems, Clinical Tests, Procedures, and Patient Goals, and that USCDI v6 includes a Care Plan data element.

Comments. Some commenters stated that our proposal for removing the care plan certification criterion and related C-CDA-based certification criteria would require transition timelines and additional guidance and safeguards to ensure continued baseline functionality. Commenters requested phased or delayed implementation, clearer transition strategies, support for participation in national exchange frameworks, or replacement criteria, such as FHIR-based care plan requirements, before removing the existing criterion.

Response. We appreciate these concerns from commenters regarding the need for timelines, strategies and resources related to transitioning from C-CDA-based exchange to FHIR-based exchange. We also understand the importance of ensuring that support for care plan functionality is continued during a transition to FHIR-based exchange. As stated above, we have extended the deadline for removal of C-CDA-based creation and transmission requirements in the transitions of care certification criterion in § 170.315(b)(1) to January 1, 2030. This extension helps provide a timeline and pathway for transition to FHIR for developers of certified health IT. As stated earlier, we

do not feel it is necessary to also maintain requirements in § 170.315(b)(9) because health IT developers are likely to continue supporting C-CDA-based exchange under § 170.315(b)(1). Additionally, we will continue to provide resources related to transitioning to FHIR-based exchange on our website. Regarding replacement criteria, we did not propose a FHIR-based replacement for the certification criterion in § 170.315(b)(9), and therefore, we are not finalizing a FHIR-based replacement here. However, as we stated in the Proposed Rule, there have been advancements in this area, and we may consider whether to propose a replacement in future rulemaking (90 FR 60986). We also note that USCDI v6 includes a Care Plan data element, which we believe may alleviate some of commenters' concerns regarding lack of continuity for care plans.

Comments. A commenter had concerns about CMS alignment.

Response. We thank the commenter for this comment. We note that currently there are no CMS requirements requiring health care providers to adopt or use health IT certified to the certification criterion in § 170.315(b)(9). Therefore, we do not believe that removal of this criterion will lead to regulatory alignment concerns for health care providers participating in CMS programs.

Comments. Commenters who supported removal of the care plan criterion stated that it would reduce burden and that the criterion is no longer tied to active regulatory program requirements or widely used. These commenters noted that the criterion had been associated with the Comprehensive Primary Care Plus (CPC+) program, which is no longer active, and that its removal would not compromise Certification Program integrity.

Response. We thank commenters for these comments in support of the proposal. We agree with commenters that removal of the certification criterion in § 170.315(b)(9) will reduce burden, including costs to maintain certification. We also agree with commenters that the certification criterion in § 170.315(b)(9) is no longer associated with an active CMS program or other incentive program and that removal will not compromise Certification Program integrity. We have finalized the proposal to remove the certification criterion in § 170.315(b)(9) as of the effective date of a final rule as proposed.

e. Decision Support Interventions

We proposed to revise the “decision support interventions” (DSI) certification criterion in § 170.315(b)(11) in order to reduce burden and promote innovation of SI in healthcare (90 FR 60986 through 60988). The DSI certification criterion ensures that users can leverage health IT for clinical decision-making by supporting their selection of both evidence-based and predictive DSIs (PDSIs) and enabling users' access to transparent information on DSI performance and quality. In particular, the source attribute requirements in § 170.315(b)(11) support “model cards” for PDSIs, which essentially function as nutrition labels and provide important information for providers using a PDSI, such as how a PDSI's algorithm was trained, its intended use and limitations, and how it performs across different patient groups. However, as discussed in more detail below, we did not find that users of certified health IT have relied on these requirements to review such information or that the requirements have positively impacted patient care (90 FR 60987). We have finalized removal of the requirements related to “model cards” as well as other revisions for the reasons discussed in detail below.

We proposed to remove the requirement in § 170.315(b)(11)(ii)(B) to enable interventions when a patient's medications, allergies and intolerance, and problems are incorporated from a transition of care or referral summary received and pursuant to paragraph § 170.315(b)(2)(iii)(D), and we proposed to redesignate the certification criterion requirement currently in § 170.315(b)(11)(ii)(C) as § 170.315(b)(11)(ii)(B). We also proposed to remove the parenthetical reference in § 170.315(b)(11)(iii) to “drug-drug and drug-allergy contraindication checking” upon the effective date of this final rule. Additionally, we proposed to revise the requirements in § 170.315(b)(11)(iii)(B), which currently relate to enabling predictive DSIs that use any data expressed in the standards in § 170.213, to limit the application of the certification criterion to just data expressed in § 170.315(b)(11)(iii)(A) as well as data expressed in the Clinical Notes and the Assessment and Plan of Treatment data classes in the standards in § 170.213. Finally, we proposed to remove the requirements in § 170.315(b)(11)(iv) and (v) regarding source attribute support, access, and modification and in § 170.315(b)(11)(vi)

regarding intervention risk management for predictive DSIs.

Comments. A large majority of commenters were not supportive of our proposal, primarily due to concerns about removing DSI transparency and risk-management requirements in § 170.315(b)(11). Concerns included that reducing transparency and accountability for SI-enabled tools would shift evaluation, governance, and liability burdens to providers and health systems and undermine patient safety, clinician trust, and the ability to evaluate bias, performance, and appropriateness. Many commenters expressed concerns that eliminating “model card” requirements in § 170.315(b)(11) was premature since the requirements have been in effect for less than two years and have not been fully evaluated. Commenters stated that removal of the model card requirements would create a significant regulatory gap in SI governance at a time when SI adoption is accelerating. Some commenters stated that providers would lose important information about intended use, provenance, training data, limitations, performance, and known risks. Some commenters stated that the loss of information would make it more difficult to determine the appropriateness of a tool for particular patient populations or settings. Another commenter noted that in behavioral health and substance use cases, reduced transparency may complicate safe and lawful use of tools that process sensitive information, creating confidentiality and compliance concerns. Several commenters noted as a distinct benefit of model cards or source attribute disclosures that funding-source disclosures help detect hidden commercial or pharmaceutical influence on CDS recommendations.

Over half of the commenters expressing concerns about transparency wanted ONC to retain the model cards requirements, or the full criterion, while the other commenters with transparency concerns wanted some form of guardrails even if model card requirements are removed. Commenter suggestions for guardrails included establishing voluntary transparency standards, creating a voluntary transparency designation for predictive SI, retaining the useful elements of predictive DSI transparency and risk management requirements, retaining the criterion in § 170.315(a)(9), clarifying developer responsibilities related to transparency, acknowledging transparency as a best practice, or public model cards as a means of ensuring transparency.

Response. We appreciate these commenter concerns and understand the importance of ensuring appropriate transparency around decision support interventions. However, as we stated in the Proposed Rule, developers of certified health IT have reported that during care delivery, most clinical users lack the time or technical background to engage with source attribute information for DSIs (90 FR 60987). Further, we have identified no evidence through peer reviewed publication or trade press indicating that users of certified health IT have relied on the transparency requirements in § 170.315(b)(11) to access, record, or modify source attributes, or that the requirements have led to positive impacts on patient care (90 FR 60987). We have also found no evidence that source attribute transparency requirements in § 170.315(b)(11) have improved healthcare delivery organizations’ evaluation and effective use of SI (90 FR 60987). We believe that we have had a sufficient amount of time to evaluate the effectiveness of the transparency requirements in § 170.315(b)(11), including via peer reviewed publication, articles in the press, and reports from developers of health IT, and are not persuaded of their value, particularly given the feedback we have received from developers that the requirements are burdensome and detrimental to innovation (90 FR 60987). We do, however, believe it is important to continue to ensure the ability for users to leverage health IT for clinical decision-making and to select both evidence-based and predictive DSIs, and we encourage users of certified health IT to discuss SI quality and performance before deploying DSIs supplied by the developer of their certified health IT. We note that removing requirements for DSI performance and quality as part of the Certification Program does not mean that such information about intended use, provenance, training data, limitations, performance, and known risks is unknown or unavailable to users of certified health IT, or that such information could not be communicated to them. We encourage users of certified health IT to ask their developers for such information, and in particular we remind users of certified health IT of the importance of complying with applicable requirements to identify potential bias in PDSIs and to avoid discrimination through the use of such tools. See 45 CFR 92.210. We note that we did not propose to remove requirements in § 170.315(b)(11)(ii)(C) for evidence-based DSIs regarding

electronic feedback data, which support transparency by enabling providers to share, export, and report on the performance of DSIs in real-world settings. We did, however, propose to redesignate § 170.315(b)(11)(ii)(C) as § 170.315(b)(11)(ii)(B).

Specifically, we have finalized as proposed revisions in § 170.315(b)(11) to remove the requirement in § 170.315(b)(11)(ii)(B); redesignate § 170.315(b)(11)(ii)(C) as § 170.315(b)(11)(ii)(B); remove the reference in § 170.315(b)(11)(iii) to “drug-drug and drug-allergy contraindication checking”; revise the requirements in § 170.315(b)(11)(iii)(B) to limit the application of the certification criterion; and remove the source attribute support, source attribute access and modification, and intervention risk management requirements in § 170.315(b)(11)(iv), (v), and (vi). While we have retained a revised CIRI certification criterion in this final rule, we believe that removal of the requirement in § 170.315(b)(11)(ii)(B) is still appropriate. The requirement prescribed enabling DSI in a specific circumstance with limited data elements (*i.e.*, transition of care/referral summary focused on only medications, allergies and intolerance, and problems). Such prescription has minimal value for certification, particularly compared to the DSI certification criterion requirement to support selection of interventions based on a wider breadth of data as identified in § 170.315(b)(11)(iii). This requirement further provides flexibility for health IT developers and their customers to determine how interventions are incorporated into customer workflows.

We acknowledge that the prior CDS “source attributes transparency” requirements (§ 170.315(a)(9)(v)) for evidence-based interventions have been part of the Certification Program for many years and may not present significant burden or costs for health IT developers with health IT previously certified to the CDS certification criterion. As such, we will further consider for future rulemaking whether these or similar requirements should be reinstated in the Certification Program.

Comments. A number of commenters expressed concerns regarding burden. Commenters stated that the proposal would shift evaluation, governance, and liability burdens related to SI tools to providers and health systems. Some commenters stated that the burden shift would be especially problematic for small, rural, safety-net, shared-network, community healthcare, and LTPAC

organizations that lack data-science, governance, legal, or IT capacity.

Response. We appreciate these concerns expressed by commenters regarding evaluation, governance, and liability burden shifting to providers and healthcare systems. We understand the importance of ensuring that additional burdens related to selecting DSIs or DSI functionality are not placed on providers and health systems. As discussed above, we did not propose removal of requirements related to feedback tools for evidence-based DSIs in redesignated § 170.315(b)(11)(ii)(B), and we believe these requirements can help provide assurances regarding the performance of evidence-based DSI functionality in Health IT Modules certified to § 170.315(b)(11). As also discussed above, we are not persuaded of the value of the transparency requirements in § 170.315(b)(11), and thus we do not believe that our finalized removal of the requirements to enable access to source attributes for evidence-based and predictive DSIs will significantly impair the ability to evaluate DSI tools. We believe the finalized revisions to § 170.315(b)(11) provide sufficient assurances and transparency to make any significant increase or shift in the evaluation, governance, or liability burden of providers and healthcare systems unlikely.

Comments. A number of commenters expressed concern that the proposal would undermine patient safety. Commenters expressed concern that the proposal would impair the ability to evaluate bias, performance, and appropriateness. Some commenters stated that the proposal could result in unsafe recommendations, preventable harm, inappropriate reliance, and weaker clinician oversight. A couple of commenters expressed concern that loss of transparency could increase automation bias, salience bias, or other overreliance problems. Several commenters expressed concern that the proposal removes a core safeguard. Several commenters also stressed that certain populations and settings need population-specific validation and transparency because they are especially vulnerable to underrepresentation or inappropriate extrapolation. A commenter expressed concern that removing the DSI reference to drug-drug and drug-allergy contraindication checking could negatively affect patient care.

Response. We appreciate these comments expressing concerns about patient safety, and we understand the importance of ensuring that the use of DSI tools does not harm patients or

negatively impact patient care. We note that, as we stated in the Proposed Rule, we are not aware of any publicly available evidence showing that transparency requirements in § 170.315(b)(11) led to positive impacts on patient care, including removal of defective algorithms (90 FR 60987). In response to commenters' concerns regarding a need for population-specific validation and transparency, we agree that such information is important, especially for patients belonging to underrepresented groups, and we encourage users of certified health IT to discuss these facets of SI quality and performance before deploying their developer's supplied PDSIs. We do not believe that our policy to remove requirements for user transparency will significantly impair efforts to evaluate DSI tools or discuss such matters with health IT developers. Regarding removal of the reference to drug-drug and drug-allergy contraindication checking, we note that, as stated in the Proposed Rule, the retention of requirements in § 170.315(b)(11)(iii)(A)(2) and (3) regarding enabling evidence-based DSIs that include "Medications" and "Allergies and Intolerances" as data types ensures support for such interaction checks by Health IT Modules certified to § 170.315(b)(11) (90 FR 60986 through 60987).

Comments. Some commenters stated that the proposal would weaken provider and patient trust in SI-enabled decision support and that this could slow responsible adoption of SI-enabled decision support.

Response. We appreciate these comments regarding trust in SI-enabled decision support. We are committed to encouraging trust in health IT and health information exchange, including trust in SI-enabled decision support. We do not believe that our revisions to § 170.315(b)(11) will significantly lessen trust in SI-enabled decision support because, as described above, we found that the requirements lacked utility. Additionally, the retained requirements related to feedback tools in redesignated § 170.315(b)(11)(ii)(B) help provide assurances regarding the performance of DSI functionality in Health IT Modules certified to § 170.315(b)(11). We believe the finalized revisions to § 170.315(b)(11) provide sufficient assurances and transparency, and that our finalized policies will not contribute to an erosion in provider or patient trust in health IT and SI-enabled DSI.

Comments. Some commenters rejected the premise that low clinician use at the point of care means the information lacks value, arguing that the real users are governance, procurement,

implementation, compliance, and safety teams.

Response. We appreciate these comments regarding clinician use of source attribute information and the value of that information. We noted in the Proposed Rule that developers of certified health IT reported that during care delivery, most clinical users did not have the time or technical background to engage with source attribute information for either evidence-based DSIs or predictive DSIs supplied by the developer of certified health IT (90 FR 60987). We recognize that there is value in transparency regarding DSIs, however we remain cognizant of the need to minimize burden on developers of certified health IT, especially when the required functionality is not widely used and may not be equally applied to other developers that do not participate in the Certification Program. We note that we have retained requirements related to feedback tools for evidence-based DSI in redesignated § 170.315(b)(11)(ii)(B), which we believe help ensure transparency.

Comments. Some commenters expressed specific concerns about removing risk-management requirements, including that it would weaken drift monitoring, control over updates and changes, auditability, root-cause analysis, and ongoing quality review.

Response. We appreciate concerns regarding the removal of risk-management requirements, including concerns related to monitoring drift, updates, auditability, root-cause analysis, and ongoing quality reviews. While we understand the importance of ensuring that predictive DSI functions appropriately and effectively, we also seek to minimize burden on developers of certified health IT and encourage innovation in this evolving area. We believe that removal of the risk-management requirements in § 170.315(b)(11)(vi) provides substantial burden relief for developers of certified health IT without hindering developer's ability to work with their customers to institute ongoing monitoring of predictive DSI performance and effectiveness. Requirements to apply risk management to supplied PDSIs may still be considered best practices and may still be incentivized through other policies, such as those established by the FDA for premarket approvals.

Comments. Several commenters expressed concern about fragmentation and variability that might occur if requirements in § 170.315(b)(11) are removed. Some commenters stated that removing the Federal framework could

produce fragmented oversight, including divergent State requirements or weaker cross-agency alignment. Several commenters stated that resulting variability across developers could make SI less portable, less comparable, or less predictable across health systems. A commenter stated that removing the requirements soon after HTI–1 implementation would undercut recent compliance investments and create regulatory instability.

Response. We appreciate these comments regarding fragmentation and variability that could occur if requirements in § 170.315(b)(11) are removed. We note that we are retaining a number of requirements in the certification criterion in § 170.315(b)(11), including requirements to support DSI selection. We do not agree that our revisions to § 170.315(b)(11) will create regulatory instability. Rather, we anticipate that by removing requirements for developers of certified health IT to supply their customers with access to DSI performance and quality information, we are reducing the Department's regulatory footprint and concentrating requirements solely within other Department authorities, such as those exerted by the FDA.

Comments. Some commenters expressed concerns about the proposal's data support and selection requirements in § 170.315(b)(11)(iii). Some commenters stated that the requirements were confusing, ambiguous, or misaligned with the FHIR API framework, especially where no clear standard for “selection” was specified. Some commenters objected to narrowing the scope of predictive DSIs because certain tools may need broader clinical context, including longitudinal history and social or behavioral context. A commenter stated that ONC needed a standard for enabling third-party predictive DSIs in § 170.315(b)(11)(iii)(B).

Response. We appreciate these comments expressing concerns regarding requirements in § 170.315(b)(11)(iii). As we stated in the Proposed Rule, we have received feedback from developers of certified health IT that requiring support of predictive DSIs that use *any* data element in one of the USCDI standards in § 170.213 is overly burdensome and costly (90 FR 60986). We also noted in the Proposed Rule that many USCDI data elements, such as phone number and phone number type data elements, are not likely to be used as inputs for predictive DSIs (90 FR 60986). We believe that revising the requirements to focus on fewer data elements will

simplify requirements and significantly reduce burden for health IT developers without diminishing users' ability to activate a wide variety of predictive DSIs (90 FR 60987). With respect to the comment regarding the need for a standard for enabling “selection” of third-party predictive DSIs according to § 170.315(b)(11)(iii), we continue to maintain a flexible and non-prescriptive posture regarding how a health IT developer supports selection of DSIs according to § 170.315(b)(11)(iii). We reiterate long-standing Certification Program expectations that health IT developers with Health IT Modules certified to § 170.315(b)(11) support a user's selection of DSIs based on whether a DSI uses specified data, and we decline to dictate how developers support selection of such DSIs at this time.

Comments. Some commenters expressed support for our proposed revisions to the DSI certification criterion. These commenters stated that the revisions would reduce burden from rarely used or overly prescriptive requirements and allow more flexible or voluntary approaches to transparency. Many supporters of our proposal noted extremely low use of the required functionality and a lack of value for clinicians at the point of care. Several supporters of our proposal stated that the SI landscape is rapidly evolving and that industry-led frameworks are more appropriate than Federal transparency requirements that could quickly become outdated. A supporter of our proposal noted that the current requirements in § 170.315(b)(11) exceed those of other Federal Government programs utilizing SI, and that the FDA is best situated to ensure SI safety. Another supporter of our proposal stated that most SI solutions function as downstream consumers of interoperable data and are not components of certified EHRs. A supporter of our proposal stated that source attribute information embedded into clinical interfaces risks alert fatigue without providing benefit to patients.

Response. We appreciate these comments in support of our proposal. We agree with commenters that our proposed revisions to § 170.315(b)(11) would reduce burden related to under-utilized requirements and allow for greater innovation in this area. We also agree that, as several commenters stated, the SI landscape is rapidly evolving and industry-led efforts to provide transparency have promise. We have finalized our proposed revisions to § 170.315(b)(11) as proposed.

Comments. Several commenters commented on issues that were out of scope for our proposal, including

broader audit trail and data preservation requirements, patient-facing notice regarding downstream SI-related uses of data, contractual issues, and support for emerging interoperability approaches beyond existing standards.

Response. We appreciate these comments; however, these comments were outside the scope of this rulemaking.

3. Clinical Quality Measures Certification Criteria

a. Clinical Quality Measures—Report

In the Proposed Rule (90 FR 60988), we proposed to revise the “clinical quality measures (CQM)—report” certification criterion in § 170.315(c)(3) as of the effective date of this final rule. This certification criterion enables a user to electronically create a data file for transmission of clinical quality measure data. In the Cures Act Interim Final Rule, we revised § 170.315(c)(3) to include a corrected compliance transition timeline for the criterion in § 170.315(c)(3)(ii), which specified the use of standards in §§ 170.205(h)(2) and (k)(1) and (2), for the period before December 31, 2022 (85 FR 70075 and 70083). In the Proposed Rule, we proposed to remove § 170.315(c)(3)(ii) because that transition time period had elapsed (90 FR 60988). We also proposed to move the requirements in § 170.315(c)(3)(i) to § 170.315(c)(3), thus removing all subparagraphs and including all certification criterion requirements in the main paragraph for § 170.315(c)(3). For further background and history on this certification criterion, we refer readers to the Proposed Rule (90 FR 60988).

Comments. The majority of commenters supported our proposal to revise the CQM—report certification criterion to remove expired transition language, stating that the proposal would streamline outdated regulatory requirements with little or no practical impact. Several of these commenters characterized the proposal as a narrow cleanup that would align the regulation with current practice and remove obsolete references to expired standards.

Some commenters used their discussion of this certification criterion to recommend broader changes to quality measurement policy, including recommending: revising § 170.315(c)(3) to permit technology-neutral quality reporting, allowing certified Health IT Modules to satisfy the certification criterion requirement using either Quality Reporting Document Architecture (QRDA) or FHIR-based quality reporting implementation guides, and establishing a transition

pathway toward FHIR-based quality reporting. A few commenters expressed concern that continued reliance on QRDA is inconsistent with FHIR-based modernization efforts because it limits quality reporting to legacy document standards. Other commenters also noted that continued reliance on QRDA-based reporting introduces architectural inconsistency with interoperability efforts that are transitioning to FHIR-based APIs and may require developers to maintain parallel infrastructure, limiting their available modernization resources. A cross-cutting concern expressed by a few commenters was that revisions to certification requirements should not risk continuity by creating a gap in quality reporting infrastructure before FHIR-based or other modernized approaches are fully implemented. Additionally, many of the commenters who recommend broader changes to quality measurement policy encouraged broader API-driven quality measurement approaches and strengthening post-certification oversight and transparency regarding the quality measurement capabilities of certified health IT products, including tracking which quality measurement capabilities are included versus offered as paid add-ons to products. A few other commenters expressed concerns regarding the continuity of quality reporting infrastructure, workflow burden and costs for providers, comparability and auditability of quality measurement outputs, maintaining a consistent baseline for interoperability and quality reporting, and supporting digital quality measures, including measures that use patient-reported data.

Response. We thank commenters for their feedback. We have finalized our proposal to revise § 170.315(c)(3), including the removal of § 170.315(c)(3)(ii) and transfer of the requirements in former § 170.315(c)(3)(i) to § 170.315(c)(3), as of the effective date of this final rule. We note that the revisions to § 170.315(c)(3) do not alter the substantive requirements a Health IT Module must meet to obtain certification to § 170.315(c)(3) that remain applicable under the CQM—report certification criterion.

We acknowledge commenters' recommendations that we use this final rule to adopt broader revisions related to quality measurement modernization efforts, including technology-neutral QRDA or FHIR-based quality reporting implementation guides, a sequenced transition pathway for broader FHIR-based quality reporting, as well as concerns expressed by commenters regarding provider burden. However, we did not propose these broader revisions

to § 170.315(c)(3) in the Proposed Rule (90 FR 60988), and therefore, we have not adopted these revisions in this final rule.

Comments. Some commenters opposed removal of the CQM—report certification criterion and recommended coordinating certification changes related to quality reporting with CMS program requirements and requested that any future substantive changes to quality reporting certification requirements include mechanisms to evaluate impacts on CMS program compliance. A number of these commenters recommended that such substantive changes to quality reporting certification requirements be delayed until 2028 or until alignment with CMS program timelines can be achieved.

Response. We acknowledge commenters' recommendations to coordinate changes to certification criteria related to quality reporting with CMS program requirements and to include mechanisms to evaluate potential impacts on CMS program compliance. We also recognize commenters' requests that substantive changes be delayed until alignment with CMS program timelines can be achieved. However, we did not propose to remove the CQM—report certification criterion, therefore, these comments are out of scope for this rulemaking. The revisions we have finalized are limited to removal of expired transition language and reorganization of regulatory text in the CFR, and they do not alter the substantive requirements a Health IT Module must meet to obtain certification to § 170.315(c)(3) that remain applicable under this certification criterion. We will continue to coordinate with CMS, as appropriate, on any future proposals to substantively change this certification criterion in future rulemaking in order to support alignment of Certification Program criteria with CMS program needs.

b. Clinical Quality Measures—Filter

In the Proposed Rule, we proposed to remove the “clinical quality measures (CQM)—filter” certification criterion in § 170.315(c)(4) with an effective date of January 1, 2027 (90 FR 60988). This certification criterion assesses whether a Health IT Module can filter quality data based on a set of standardized data elements for electronic clinical quality measures (eCQM) calculated using certified health IT. As stated in the Proposed Rule (90 FR 60988), we proposed to remove this certification criterion because we identified that the administrative costs of certification for CQM—filter are no longer offset by the benefits of advancing the specific

functionality supported by the criterion. Additionally, quality reporting programs, such as those required by States and CMS programs, require broader supplemental data and capabilities beyond what we currently require for certification. We also stated in the Proposed Rule (90 FR 60988) that health IT developers have widely implemented technology solutions that expand beyond the baseline requirements of the CQM—filter certification criterion. We further stated that § 170.315(c)(4) is not included in the Base EHR definition in § 170.102 but is included in the CEHRT definition used by programs including MIPS in 42 CFR 414.1305. We clarify here that § 170.315(c)(4) is specified as optional for inclusion as part of CEHRT necessary to report on clinical quality measures in paragraph (2) of the definition. We also explained that health care providers participating in CMS alternative payment models, as well as health IT developers supporting quality initiatives, reported using different options to filter eCQM results, including customized systems and support from third parties to meet particular quality measure reporting needs. For further background and history on this certification criterion, we refer readers to the Proposed Rule (90 FR 60988).

Comments. Many commenters opposed the removal of the CQM—filter certification criterion. These commenters expressed concerns that removal could shift responsibility for maintaining quality reporting, stratification, and workflow functionality from health IT developers to clinical providers, increase provider burden and costs, require manual workarounds or third-party tools, and reduce comparability and confidence in quality measure outputs across systems. Some commenters recommended that we not remove the CQM—filter certification criterion until a fully functional, low cost, standardized replacement is available, noting that § 170.315(c)(4) serves as a baseline capability supporting consistency across systems.

Several commenters representing providers stated that the CQM—filter certification criterion is important for day-to-day quality reporting workflows and for supporting some Federal, State, and other programmatic reporting requirements. Another commenter specified that these reporting workflow functions support demographic stratification, validating measure denominators and numerators, generating clinician-facing lists for gap closure, and reconciling measure

discrepancies across systems. Several commenters, including payer- and plan-affiliated organizations, echoed concerns expressed by providers, particularly with respect to workflow integration and the potential for disruption to existing reporting processes, including for safety-net providers and organizations that rely on certified functionality to support Uniform Data System (UDS) and other program reporting requirements.

Response. We thank commenters for their feedback. We have finalized our proposal to remove the CQM—filter certification criterion in § 170.315(c)(4) with an effective date of January 1, 2027.

We continue to believe that the administrative costs of certification for § 170.315(c)(4) are no longer offset by the benefits of maintaining this specific certification requirement. As noted in the Proposed Rule (90 FR 60988), quality reporting programs generally require broader supplemental data and capabilities than the limited functionality described in § 170.315(c)(4), and health IT developers have widely implemented technological solutions that extend beyond the criterion's minimum certification requirements.

While we recognize the importance of functionality within EHRs to filter quality data by common variables, current rates of certification indicate that such functionality is not being driven by compliance with this certification criterion. As of May 2026, CHPL³⁰ data indicates there is low interest by health IT developers in certifying their Health IT Modules to § 170.315(c)(4). For example, there are 326 active Health IT Modules certified to § 170.315(c)(1), (2), or (3), but only 62 active Health IT Modules certified to § 170.315(c)(4). Additionally, we find from publicly available 2024 Promoting Interoperability data that less than 2 percent of MIPS-eligible clinicians and less than 8 percent of eligible hospitals and critical access hospitals reported using health IT certified to the CQM—filter certification criterion, showing that few healthcare providers used technology certified to this criterion.^{31 32} These findings are consistent with feedback received through listening sessions with a wide range of health care provider types and sites of service,

as well as through public correspondence.

We appreciate comments recommending that we do not remove this certification criterion until a fully functional, low cost, standardized replacement is available. However, based on the utilization data described above, removal of the CQM—filter certification criterion is not expected to result in a decrease in the availability of quality measure filtering functionality in health IT, as developers and users have existing options to support filtering and stratification functions beyond the limited functionality described in § 170.315(c)(4).

We acknowledge concerns expressed by commenters surrounding the importance of supporting reliable and efficient quality measure data reporting workflows across Federal, State, and other programmatic reporting requirements. We also acknowledge that some providers, particularly safety-net providers and organizations with limited resources, may rely on filtering functionality within their EHRs to support specific reporting workflows, including those related to UDS reporting. Additionally, we acknowledge concerns expressed by commenters that removal could shift responsibility for maintaining quality reporting functionality from health IT developers to clinical providers resulting in an increase in provider burden. However, given the low rates of certification to this criterion, we believe health IT developers provide this functionality in response to customer needs, rather than to obtain certification for their Health IT Modules to this certification criterion. Therefore, we do not believe removing the availability of § 170.315(c)(4) for certification will result in a loss of quality measure filtering functionality from health IT systems, in a shift of responsibility from health IT developers to clinical providers, or in a potential disruption to workflow integration or existing reporting processes. We also do not believe that removing the CQM—filter certification criterion will increase provider burden and costs, require additional manual workarounds or third-party tools, or affect existing comparability and confidence in quality measure outputs across systems. As noted in the Proposed Rule (90 FR 60988), developers and providers have implemented a range of approaches to support filtering, stratification, and validation functions that extend beyond the limited baseline established by this certification criterion.

Comments. Some commenters who opposed removal of the CQM—filter

certification criterion recommended a transition plan instead of immediate removal of the criterion. A commenter recommended that any changes to certification requirements should allow a two-year window of voluntary compliance following publication of a requirement in final rulemaking. Several commenters recommended a phased or delayed sunset in coordination with CMS program timelines. A few of these commenters recommended we adopt a phased transition as more standardized approaches to digital quality measurement and API-based quality data exchange mature.

Response. We appreciate commenters' requests that we coordinate the timing of removal of the CQM—filter certification criterion with CMS program timelines and future quality measure modernization efforts. We acknowledge the cross-cutting concern expressed by commenters; however, the certification criterion is specified as optional under the definition of CEHRT in 42 CFR 414.1305, which is referenced by certain CMS programs, including MIPS. As a certification criterion that may "optionally" be included in the definition of CEHRT with respect to criteria necessary to support the calculation and reporting of clinical quality measures, health care providers are not subject to program requirements to use EHR technology certified to this criterion in order to meet the definition of CEHRT in 42 CFR 414.1305. Additionally, in the "Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program" (CY 2027 Physician Fee Schedule Proposed Rule) (91 FR 43842, July 16, 2026), CMS proposed to remove the reference to § 170.315(c)(4) for the CY 2027 performance period/2029 MIPS payment year, such that this certification criterion would no longer be included in the definition of CEHRT, effective January 1, 2027 (91 FR 44170).

We will continue to coordinate with CMS to ensure alignment between the definition of CEHRT and our final policy with respect to the certification criterion in § 170.315(c)(4). We are not aware of any Federal programs that require use of technology certified to this criterion. At the same time, low rates of certification to the CQM—filter criterion across health IT products, combined with feedback that this functionality is valuable and widespread in health IT systems, indicate that current functionality for

³⁰ <https://chpl.healthit.gov>.

³¹ <https://healthit.gov/data/datasets/certified-health-information-technology-reported-clinicians-promoting/>.

³² <https://healthit.gov/data/datasets/certified-health-information-technology-reported-by-hospitals-for-promoting-interoperability-performance/>.

filtering is being deployed by health IT developers without obtaining certification to this criterion. Accordingly, removal of this certification criterion should not result in a gap in functionality or otherwise necessitate a two-year window of voluntary compliance or a phased or delayed sunset. Therefore, we have finalized our proposal to remove § 170.315(c)(4), effective January 1, 2027.

Comments. A smaller number of commenters expressed support for removing § 170.315(c)(4), citing low adoption and limited current utility or value, including because this certification criterion no longer supports current CMS program needs.

Response. We thank commenters for their feedback and agree that because this certification criterion no longer supports current CMS program needs, and CHPL data demonstrates low interest among health IT developers, that removal of this criterion is appropriate.

4. Privacy and Security Certification Criteria

We proposed to remove all the privacy and security (P&S) certification criteria in § 170.315(d) and the associated Privacy and Security Certification Framework (P&S Certification Framework) under § 170.550(h) as of the effective date of this final rule. We proposed to remove the P&S certification criteria and P&S Certification Framework for a multitude of reasons that led to our conclusion that the costs and burden of these certification criteria and Certification Program requirements far exceed their intended purpose and benefits (90 FR 60989–60990). We reiterate these reasons below.

First, we have found that health IT developers have changed their development processes to build in P&S capabilities to meet these certification requirements rather than attempting to demonstrate that their technology could interface with other health IT that provides these capabilities. This has led to negative experiences for health care providers who have sought to use a best-of-breed, non-certified security technology to work across their deployed enterprise (e.g., a third-party audit log).

Second, certified health IT (which is generally EHR-focused technology) is often implemented in enterprise-wide settings (e.g., group practices, large healthcare systems, multi-provider cloud-supported services). However, it cannot, in isolation or independently, provide the necessary P&S capabilities

across all relevant technologies in the enterprise-wide setting for covered entities to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule (45 CFR part 160 and subparts A and C of part 164).

Third, while certified health IT has always been “linked” to the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, those programs have not required participating health care providers to use or implement the P&S capabilities included in certified health IT for purposes of meeting the security risk analysis measure. Rather, the health care providers must “have” such certified health IT. As such and as discussed in more detail below (and in the Proposed Rule), health care providers participating in the Medicare Promoting Interoperability Program or the MIPS Promoting Interoperability performance category are required to adopt certified capabilities that they may not use because, for example, they may prefer a non-certified security health IT product to meet their overall security needs, including compliance with the HIPAA Security Rule.

Fourth, many interested parties have overinterpreted the Certification Program’s limited scope and policy purpose with respect to health IT security and instead have assumed that the Certification Program assessed discrete specific security capabilities at significant depths, such as when and how the capabilities are implemented in health care provider or system settings. For example, interested parties have expressed incorrect expectations of certified health IT and developers, such as expectations that the Certification Program required health IT developers of certified health IT to implement and conduct penetration testing of certified health IT or ensure that certified authentication and authorization capabilities protect against known or unknown vulnerabilities. In contrast, to allow for significant scalable deployment flexibility, a certified Health IT Module must only, for example, demonstrate support for basic authentication and role-based access control.

Fifth, there remains a disconnect between health IT certified to the P&S certification criteria under the Certification Program and the implementation and compliance responsibilities of most purchasers and users of certified health IT with the requirements of the HIPAA Privacy³⁴

³⁴ 45 CFR part 160 and subparts A and E of part 164.

and Security Rules. This disconnect has led to the introduction of unnecessary regulatory burden and duplication, as well as unwarranted opportunity costs for innovation. As we noted above and in our prior rulemakings related to the P&S certification criteria, the adoption of health IT certified to the P&S certification criteria does not guarantee compliance with the requirements of the HIPAA Privacy and Security Rules. Further, the adoption of health IT certified to the P&S certification criteria does not serve as an affirmative defense, has not been identified as a mitigating factor in assessing HIPAA civil money penalties, and does not exempt a HIPAA-regulated entity from having to comply with any applicable provision of the HIPAA Privacy or Security Rules (or the HIPAA Breach Notification Rule³⁵). These facts alone have created unnecessary burden for health care providers that adopt certified health IT and health IT developers of certified health IT that also meet the definition of a covered entity or business associate, respectively, and are subject to the HIPAA Privacy and Security Rules.³⁵ In fact, we have heard from interested parties both arguing that our certification requirements go beyond the HIPAA Security Rule requirements (75 FR 44619, 80 FR 62707) or do not go far enough in meeting the requirements of the HIPAA Privacy Rule and Security Rule (80 FR 62691, 62706). Considering these opposing perspectives, our Certification Program requirements may be diverting financial resources and efforts from innovative, agile, and comprehensive solutions that can address the threats faced by health care providers and meet their regulatory obligations under the HIPAA Privacy and Security Rules. As highlighted in the Proposed Rule, by removing the P&S certification requirements under the Certification Program, we would provide health IT developers with the flexibility to innovate in this area and to develop new solutions to address the needs of their customers. Such an approach should also spur competition and give health care providers, including small practices, the opportunity to choose the best P&S technologies that fit their needs at the best price as opposed to being forced to accept those capabilities included in certified health IT that may not fit their health information P&S needs for various reasons. Finally, we noted that we did not plan to completely forego the adoption of P&S capabilities within the

³⁴ 45 CFR part 160 and subpart D of part 164.

³⁵ 45 CFR 160.103 (definitions of “covered entity” and “business associate”).

Certification Program. Instead, going forward, we stated that we intend to prioritize the adoption of P&S capabilities that are fit for purpose, use case specific, and deliver much needed technical consistency in the market when paired with specific conformance requirements. As an example, we stated that as we pursue more API-focused certification criteria, if the standards and implementation guides adopted for them do not specify or leave optional specific security requirements, we may look to add further constraints (e.g., multi-factor authentication support). Further, we stated that, in all cases, we intended to make security capability conformance a built-in part of a certification criterion's conformance and not the separate and stand-alone conformance assessment that currently exists.

In lieu of removing, on the effective date of this final rule, all of the P&S certification criteria in § 170.315(d) and the associated P&S Certification Framework under § 170.550(h), we offered an alternative proposal. We proposed to retain the “auditable events and tamper resistance” (§ 170.315(d)(2)), “audit report(s)” (§ 170.315(d)(3)), and “auditing actions on health information” (§ 170.315(d)(10)) certification criteria and associated P&S Certification Framework certification requirements. We stated that these certification criteria and included functionality may serve to help identify fraud and abuse. We noted that the functionality may also support health care provider compliance obligations and investigations by relevant entities, including both civil and criminal matters at the Federal and State levels. As mentioned in the Proposed Rule, identifying and addressing fraud and abuse increases confidence in the nation's healthcare system, reduces inappropriate and wasteful spending, and protects taxpayer dollars when it comes to government spending on healthcare (90 FR 60990).

Comments. We received some comments supporting our proposal to completely remove the P&S certification criteria and the associated P&S Certification Framework. These commenters strongly agreed with our rationale, including noting that removal would eliminate regulatory duplication. These commenters asserted that certification involved intensive and costly testing. Some of these commenters also advocated for a “system-wide approach” to certification and a uniform national governance structure for privacy and security. Another commenter highlighted the

availability of alternative certification processes, such as HITRUST.

Response. We thank commenters for their feedback. We have ultimately decided not to finalize our proposal to remove the P&S certification criteria and the P&S Certification Framework for the reasons we discuss hereafter.

Comments. The vast majority of commenters did not support our proposal to remove all of the P&S certification criteria and the P&S Certification Framework. With limited exceptions, these commenters generally did not comment on or respond to our rationale for proposing to remove the P&S certification criteria and the P&S Certification Framework. Rather, they offered different rationales for keeping the P&S certification criteria and P&S Certification Framework. Commenters stated that certification provides a minimum baseline of P&S capabilities and a mechanism for verifying that these capabilities exist in health IT products that health care providers purchase, license, and use. Further, health care providers expressed concern that removal of the certification requirements will both shift burden to health care providers to verify the existence of the capabilities and lead to developers removing P&S capabilities due to costs and burden. These concerns were particularly acute for small and rural providers that stated they had limited resources to address these concerns and negotiate inclusion of capabilities in health IT. A few commenters asserted that privacy and security capabilities also support patient safety (e.g., ensuring health information remains reliable).

Commenters who responded to our rationale that P&S certification criteria do not guarantee compliance with the requirements of the HIPAA Privacy and Security Rules, do not serve as an affirmative defense, have not been identified as a mitigating factor in assessing HIPAA civil money penalties, and do not exempt a HIPAA-regulated entity from having to comply with any applicable provision of the HIPAA Privacy or Security Rules, recommended that we work with the HHS Office for Civil Rights to find ways to leverage the adoption and use of health IT certified to P&S certification criteria for compliance with the HIPAA Privacy and Security Rules.

In response to our alternative proposal, commenters expressed strong support for retaining the three “auditing” certification criteria. However, many of these same commenters pointed out that the criteria-incorporated audit standard

(ASTM E2147–18) is outdated and should be updated.

Some commenters argued for the specific retention of other P&S certification criteria such as the authentication (§ 170.315(d)(1)) and encryption (§ 170.315(d)(7) and (9)) criteria.

A few commenters suggested using testing alternatives to lower burden.

Response. We appreciate the robust response from commenters and their strong views in favor of preserving the P&S certification criteria and the P&S Certification Framework. As noted above, commenters generally did not respond to our rationale for removal. Further, we were not persuaded by the comments that did respond to some of our rationale because we expect that developers would remove P&S capabilities that are redundant or could be replaced by a health care provider with a better alternative and this would be preceded by discussions with customers (e.g., health care providers). However, we have reassessed our proposals in light of commenters' explanations for why we should retain some (and update) P&S certification criteria. As we stated in the Proposed Rule, we have always supported strong P&S health IT infrastructure and plan to continue to incorporate P&S capabilities into the Certification Program. The Proposed Rule did not address all potential options for revisions to the P&S certification criteria and the P&S Certification Framework. Rather, it focused primarily on a binary choice between removing all the P&S certification criteria and P&S Certification Framework (with a discrete alternative proposal focused on three P&S certification criteria) or not. We have decided not to finalize our proposal to remove any of the P&S certification criteria, the P&S Certification Framework, or the alternative proposal to retain the “auditing” certification criteria only. We will continue to consider the best regulatory approach for the P&S certification of health IT under the Certification Program in anticipation of future rulemaking. This will also provide additional time to consider comments related to alignment of the P&S certification of health IT under the Certification Program with policies and requirements of the HIPAA Privacy and Security Rules. Future rulemaking may include proposing to remove all or some P&S certification criteria, updating certain P&S certification criteria, changing the P&S Certification Framework, or other options to address the concerns we have expressed in this

rulemaking and those concerns raised by commenters.

We also draw readers' attention to the fact that we did not include the following certification criteria in the P&S Certification Framework when we adopted the criteria: § 170.315(g)(31) "provider prior authorization API—coverage requirements discovery"; § 170.315(g)(32) "provider prior authorization API—documentation templates and rules"; § 170.315(g)(33) "provider prior authorization API—prior authorization support"; § 170.315(j)(20) "workflow triggers for decision support interventions—clients"; and § 170.315(j)(21) "subscriptions—client." As part of any future rulemaking, we will consider whether to add them to the P&S Certification Framework if such framework is retained or revised.

5. Patient Engagement Certification Criteria

a. View, Download, and Transmit to a 3rd Party

We proposed to revise the "view, download, and transmit to 3rd party" (VDT) certification criterion in multiple ways. We proposed to remove the Web Content Accessibility Guidelines (WCAG) conformance requirement from the certification criterion (found in § 170.315(e)(1)(i)). We proposed to remove the VDT requirement in § 170.315(e)(1)(ii)(A)(2) to conform with any Network Time Protocol (NTP) standard for purposes of "date and time each action occurred" under the activity log. Finally, we proposed the following conforming revisions: (1) remove and reserve § 170.315(e)(1)(i)(A)(1) because the requirement had an expiration date of December 31, 2025; revise § 170.315(e)(1)(i)(B)(1) and (2) to remove references to § 170.205(a)(5) because the standard codified in these paragraphs also had an expiration date of December 31, 2025; and provide a heading for the paragraph at § 170.315(e)(1)(i), which would be "general" and would align with the Office of the Federal Register (OFR) Drafting Handbook. In the Proposed Rule, we noted that the proposed revisions, if finalized, would be effective as of the effective date of this final rule.

WCAG

Comments. Comments from developers of certified health IT supported removing the WCAG standard and conformance requirement. These commenters noted that the WCAG conformance requirement appears duplicative and redundant with accessibility requirements imposed

elsewhere, most specifically the nondiscrimination requirements rooted in section 1557 of the Patient Protection and Affordable Care Act ("Affordable Care Act"). These commenters also emphasized that removing the outdated standard and conformance requirement would reduce certification burden and provide design flexibility.

The majority of commenters argued that we should not remove the WCAG standard and conformance requirement. These commenters asserted that certification provides explicit compliance verification and reinforces existing Federal obligations. Commenters also suggested that developers would stop including accessibility requirements and would charge more for accessibility tools. A commenter asserted that not all developers are subject to the Americans with Disabilities Act of 1990 (ADA) obligations. Some commenters contended that removing the conformance requirement would shift burden to health care providers. A few commenters suggested that removal of the WCAG conformance requirement would have a negating impact on patient access and usability.

Response. We appreciate the comments submitted that supported and opposed our proposal. We recognize that the WCAG conformance requirement in the Certification Program served a function distinct from the obligations imposed by Federal civil rights laws because certification provides an evaluation of specified health IT functionality, while the other laws impose obligations on entities covered by those laws. We also considered commenters' concerns that removing the certification requirement could reduce accessibility for patients with disabilities or place greater responsibility on health care providers to evaluate the accessibility of the health IT they purchase and use. Overall, we disagree with and are not persuaded by the commenters that opposed our proposal.

As noted in the Proposed Rule, the baseline certification standard of WCAG 2.0 Level A was adopted with the 2014 Edition in 2012 and has been part of the voluntary Certification Program and specifically the VDT certification criterion since that time. The functionality is now sufficiently widespread among certified health IT and health care providers who adopt such technology. This is true because the VDT certification criterion has been part of the CEHRT definitions and specifically supports the "Provide Patients Electronic Access to their Health Information" measures under the

Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category since the 2014 Edition. By removing the WCAG conformance requirement (WCAG 2.0, Level A or optional Level AA), developers of health IT currently certified to § 170.315(e)(1) will likely not abandon accessibility functionality for that certified health IT. Rather, they will have the opportunity to consider other innovative ways to provide patients with accessible viewing functionality. In short, the purpose of certification under the Certification Program has been achieved in drawing attention to accessibility design and in establishing a baseline functionality for such design.

Further, as we noted in the 2011 Edition Interim Final Rule and again in response to comments on the 2011 Edition Interim Final Rule, in providing patients with access to their online health information, the accessibility requirements of the ADA and Section 504 of the Rehabilitation Act of 1973 still apply to entities covered by these Federal civil rights laws (75 FR 2036, 75 FR 44643). In addition, this final rule does not alter the obligations of any entity under the ADA,³⁶ Section 504 of the Rehabilitation Act,³⁷ Section 1557 of the Affordable Care Act,³⁸ or any other applicable Federal or State law.

Even if a developer of certified health IT was not covered by relevant laws as suggested by a commenter, we expect developers to include, as requested by their clients (e.g., health care providers), accessibility functionality needed to support their clients' compliance with applicable laws. In response to commenters' suggestions that the removal of the WCAG conformance requirement will increase both burden and costs for health care providers, we respectfully disagree. We recognize commenters' concern that removing the WCAG conformance requirement could place greater responsibility on health care providers to evaluate the accessibility of the health IT they purchase and use for compliance with relevant laws. However, the legal obligations of health care providers under applicable disability and accessibility laws are not affected by this final rule. In addition, costs of certification to the adopted WCAG standard are likely built into the certified health IT licensed or purchased by the health care provider. Costs for such functionality are also likely to be

³⁶ 42 U.S.C. 12101 *et seq.*

³⁷ 29 U.S.C. 794; 45 CFR Part 84.

³⁸ 42 U.S.C. 18116; 45 CFR Part 92.

the same or less if purchased or licensed without certification.

For all these reasons, we expect health IT developers will continue to provide accessibility functionalities within their products certified to the VDT certification criterion and have finalized our proposal to remove the WCAG conformance requirement from the certification criterion (found in § 170.315(e)(1)(i)).

Comments. A commenter encouraged ONC to consider revising the certification requirement to an attestation-based approach. Another commenter suggested that we adopt a functionally equivalent, testable accessibility baseline. Some commenters suggested further revising the criterion to withdraw the “view” requirements enumerated under subparagraph (i)(A) to have the flexibility to support basic “viewing” in more innovative and user-friendly formats and methods, while retaining the ability to “download” and “transmit” health information in the standardized HL7 CDA C–CDA document format for interoperability purposes. Another commenter suggested that we removed the VDT criterion completely.

Response. These comments were outside the scope of the proposal and were not considered for finalization.

Network Time Protocol

Comments. We received few comments on the proposal to remove the NTP conformance requirement. Those comments directly focused on the proposal offered support for removing the NTP conformance requirement. Commenters stated that aligning with a NTP standard was an established industry functionality. Commenters also noted that time synchronization is handled at the infrastructure or operating-system level; and that most environments already maintain accurate time through domain controllers or equivalent mechanisms. Commenters also expressed agreement with our assessment that certification adds little value and that developers will continue using NTP regardless of conformance requirements.

Response. We thank commenters for their support. As noted in the Proposed Rule and supported by comments received on the Proposed Rule, the NTP functionality is not native to the EHR technology (rather part of the operating system within which the EHR technology runs) and unnecessary for certification because EHRs use of underlying operating system clocks is commonplace. Consistent with our overall goal to reduce regulatory burden, we agree that there is currently little

value, and unnecessary burden, in maintaining the conformance requirement as part of certification. As noted in the Proposed Rule and confirmed by developers in comments of the Proposed Rule, we do not expect that developers will stop using NTP with their certified health IT. Rather, we expect that developers will continue to use NTPs, due to ongoing evolution in the industry. Accordingly, we have finalized our proposal to remove the NTP requirements from the VDT certification criterion.

Conforming Proposals

We did not receive any comments opposing our proposed conforming revisions to the VDT certification criterion. Therefore, we have finalized the conforming revisions as proposed. We have removed and reserved § 170.315(e)(1)(i)(A)(1) because the requirement expired on December 31, 2025. We have revised § 170.315(e)(1)(i)(B)(1) and (2) to remove references to § 170.205(a)(5) because the standard codified in these paragraphs expired on December 31, 2025. We have provided a heading for the paragraph at § 170.315(e)(1)(i), which is “general.” This heading approach aligns with similar level paragraphs that have headings (§ 170.315(e)(1)(ii) and (iii)) and is compliant with the OFR Drafting Handbook.

We note that we have also corrected a grammatical error in § 170.315(e)(1)(i)(A)(6)(i) by removing “specified all the data.” The provision now reads as follows: (i) The information for a test report as specified in 42 CFR 493.1291(c)(1) through (7). It previously read as (i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7).

All revisions to the VDT certification criterion are effective as of the effective date of this final rule.

b. Patient Health Information Capture

We proposed to remove and reserve the “patient health information capture” certification criterion in § 170.315(e)(3) with an effective date of January 1, 2027. The patient health information capture certification criterion allows health care providers to incorporate unstructured patient generated health data or data from a non-clinical setting into a patient record. The criterion is not currently included in the Base EHR definition; however, the criterion is included in the definitions of CEHRT established by CMS in 42 CFR 495.4 and 42 CFR 414.1305 for programs including the Medicare Promoting Interoperability

Program and the MIPS Promoting Interoperability performance category.

We have reviewed and evaluated the patient health information capture certification criterion in § 170.315(e)(3) and sought to identify ways to reduce burden while still supporting our policy goals. As we have stressed in prior rulemaking, we take an incremental approach to improving health IT interoperability and performance, relying on factors such as market prevalence and industry readiness to harmonize current and future standards and phase out standards and certification criteria as needed (75 FR 2021).

As we mentioned in the Proposed Rule, removing the patient health information capture certification criterion in § 170.315(e)(3) on January 1, 2027, would reduce administrative burden as well as burden for health IT developers of certified health IT and health care providers while still allowing us to achieve our policy goals (90 FR 60991 and 60992).

Comments. Of the commenters who specifically commented on the patient health information capture proposal, they were generally evenly split on supporting or not supporting removal of the patient health information capture certification criterion (§ 170.315(e)(3)) with those in support noting that it would reduce burden by eliminating a criterion they described as widely implemented, poorly defined, or not delivering value.

Commenters not supporting removal (or recommending delay/retention) expressed concerns that removing the criterion could reduce support for incorporating patient- and caregiver-contributed information (including unstructured patient-generated health data) in certain settings, including Long Term and Post Acute Care, weaken patient engagement and accessibility, and create challenges for providers seeking to meet other program and interoperability expectations. Another commenter, who did not support the removal, recommended that we add the patient health information capture certification criterion to the Base EHR definition in § 170.102.

In particular, commenters noted that our proposal for removing the patient health information capture criterion would require additional guidance or specification of transition planning and impact evaluation (including coordination with other Federal program requirements). A commenter stated that ONC would also need to clarify how the shift toward FHIR-based APIs would support family caregiver access, including proxy access

mechanisms, delegation workflows, and caregiver-contributed data capture through third-party applications.

Another commenter suggested delaying the removal of the criterion until at least 2028 to support alignment with CMS requirements.

Response. We thank commenters for their input and support of our proposal to remove the patient health information capture certification criterion. We have finalized the removal of the patient health information capture certification as proposed with an effective date of January 1, 2027. As mentioned in the Proposed Rule and supported by a number of commenters, the capabilities described in the criterion are widely implemented and used in health IT at this time, suggesting that these capabilities will remain in health IT products even if the corresponding criterion is removed from the Certification Program (90 FR 60991). We also noted in the Proposed Rule that removing the criterion from the Certification Program could spur greater development and innovation in this area (90 FR 60991). We stated that there are other certification criteria that support patient engagement, such as the “view, download, and transmit to 3rd party” and “standardized API for patient and population services” certification criteria (90 FR 60991). We have seen developers integrate the functionality in the patient health information capture certification criterion as part of other patient engagement features, such as patient portals. With these considerations in mind, we believe removing this criterion from the Certification Program will help reduce burden and costs, while also spurring further innovations in patient engagement (90 FR 60991).

Because the certification criterion in § 170.315(e)(3) is a requirement for CEHRT definitions established by CMS, we proposed to remove the patient health information capture certification criterion in § 170.315(e)(3) effective January 1, 2027 (90 FR 60991), and we have finalized this date for removal in this final rule. Because patient health information capture is a requirement of the CEHRT definition, and both the Medicare Promoting Interoperability program and the MIPS program are on a calendar year rulemaking cycle, it is appropriate to align changes to the certification criteria that are included in the definition of CEHRT to a calendar year cycle as well. In the FY 2027 IPPS/LTCH PPS proposed rule, CMS proposed to update the definition of CEHRT in 42 CFR 495.4 to remove the cross-reference to the certification criterion in § 170.315(e)(3) (91 FR

19620). CMS finalized this proposal in the FY 2027 IPPS/LTCH PPS final rule, which appeared in the **Federal Register** on August 4, 2026 (91 FR 50033). CMS made similar proposals for the definition of CEHRT in 42 CFR 414.1305 in the 2027 Physician Fee Schedule proposed rule (91 FR 43842). This final action and proposed policy will (or would in the case of proposed policies) enable CMS to ensure that requirements in the definitions of CEHRT are updated to align with our final policy regarding the removal of this certification criterion. ONC will continue to coordinate with CMS to ensure alignment around changes resulting from the policies in this final rule.

We also appreciate commenters who opposed removal or recommended delaying removal based on concerns about patient- and caregiver-contributed information (including unstructured patient-generated health data) in Long Term and Post Acute Care settings, patient engagement, accessibility, and providers' ability to meet other program and interoperability expectations. We recognize the importance of enabling patients, families, caregivers, and other authorized representatives to contribute information. However, we do not believe that continued certification to § 170.315(e)(3) is necessary to preserve or advance those capabilities. The removal of the certification criterion does not prohibit health IT developers from continuing to offer these functions, does not prevent providers from using or procuring such capabilities, and does not limit the ability of health IT products to support patient- or caregiver-contributed information. Rather, removal means that this specific functionality will no longer be addressed through a certification criterion under the Certification Program. We acknowledge commenters' specific concerns regarding family caregiver access, proxy access, delegation workflows, and caregiver-contributed data capture through third-party applications. We agree that these are important use cases. However, § 170.315(e)(3) does not establish detailed requirements for proxy access, caregiver delegation, identity proofing, authorization management, or application-based caregiver contribution workflows. Retaining this criterion would therefore not, by itself, ensure that those more specific capabilities are available or implemented consistently across health IT products. We also decline to add the patient health information capture certification criterion to the Base EHR definition in § 170.102. Because we are finalizing

removal of § 170.315(e)(3), adding the criterion to the Base EHR definition would be inconsistent with our determination that the availability of a certification criterion for this specific functionality is no longer necessary. The Base EHR definition reflects certification capabilities that remain necessary as a minimum foundation for certified health IT. Based on the widespread implementation of this functionality, the availability of other patient engagement and API criteria, and the burden associated with maintaining certification to § 170.315(e)(3), we do not believe this criterion should be added to the Base EHR definition. We also considered the recommendation to delay removal until at least 2028. We do not believe a further delay is necessary. The January 1, 2027, effective date allows for regulatory alignment with CMS program requirements under the CEHRT definitions while avoiding the continued burden of maintaining a certification requirement that no longer provides sufficient incremental value. Extending the criterion beyond that date would prolong certification and compliance costs for developers and providers without materially advancing patient engagement beyond what is already supported through existing product functionality, other certification criteria, and applicable Federal policies. ONC has a history of recognizing the importance of patient engagement as a core component of modern healthcare, driving improved outcomes, enhanced safety, and lower costs by leveraging technology and intends to continue doing so with future policies. The ONC Cures Act Final Rule implemented parts of section 4006(a) of the Cures Act to support patients' access to their EHI in a form convenient for patients, such as making a patient's EHI more electronically accessible through the adoption of standards and certification criteria and the implementation of information blocking policies that support patient electronic access to their health information at no cost (85 FR 25644). Specifically, the ONC Cures Act Final Rule supported patient access to their health information by: (1) enabling patients to securely access their EHI using smartphone applications of their choice through standardized APIs; (2) emphasizing under the information blocking “fees exception” that an actor's practice of charging for the electronic access to EHI by a patient, their personal representative, or another person or entity designated by the patient, would be inherently suspect under an information blocking review; and (3)

permitting actors regulated by the information blocking regulations to educate and advise individuals about privacy and security risks posed by applications they use to steward their information while also fully supporting an individual's right to choose which application(s) they want to share their EHI with—if any. The HTI–1 Final Rule further supported patients by requiring developers certified to the “view, download, and transmit to 3rd party” certification criterion to support an “internet-based method” for patients to request a restriction on the use or disclosure of their data (89 FR 1299). We will continue to prioritize patient and caregiver engagement and monitor future developments. ONC seeks to further the advancement of patient engagement by promoting electronic access to health data and increasing resources dedicated to curbing the practice of information blocking.³⁹

6. Public Health Certification Criteria

a. Transmission to Cancer Registries

We proposed to remove and reserve the “transmission to cancer registries” certification criterion in § 170.315(f)(4) with an effective date of January 1, 2027. This criterion assesses whether a Health IT Module can properly create and format cancer case information for electronic transmission according to a CDA-based implementation specification for reporting to public health agencies. We stated that removing the certification criterion in § 170.315(f)(4) would reduce burden and encourage ongoing evolution in cancer registry reporting by offering health IT developers space to move toward FHIR standards and modern reporting solutions, further encouraging innovation.

Comments. The large majority of commenters were not supportive of removing the transmission to cancer registries certification criterion in § 170.315(f)(4), primarily due to the criterion aiding in developers' support of cancer registry reporting and concern that FHIR-based replacements are still under development and not yet sufficiently tested, adopted, implemented, or operationally ready to serve as a successor for the criterion. A commenter who stated they had participated in pilot testing of current FHIR resources for cancer reporting stressed that the current FHIR resources have potential but are not yet ready for broad operational deployment. Some commenters stated that many receiving public health systems are not ready to

operationalize FHIR at scale. Several commenters stated that the current CDA-based reporting approaches are still necessary and relied upon by registries and providers, and the criterion encourages developers to support cancer registry reporting functionality. Many commenters expressed support for moving toward FHIR-based solutions but stated that we should retain the current CDA-based criterion until FHIR is consistently implemented by providers and cancer registries and can be included in an updated criterion. Commenters expressed concerns that removal of the certification criterion would disrupt timely, complete, and standardized cancer case reporting, create a reporting gap, and shift burden to providers and public health registries.

Response. We thank commenters for expressing these concerns regarding removing the certification criterion in § 170.315(f)(4), including concerns that developers would no longer support cancer registry reporting and that standardized reporting and interoperability would be disrupted. We also appreciate the concerns regarding public health systems and FHIR readiness. In light of issues raised by commenters and our reconsideration of the proposal in response thereto, we have decided not to finalize the proposal to remove the certification criterion in § 170.315(f)(4). However, we also agree with the multiple comments supporting movement toward FHIR-based solutions, and we have confidence in the future progression of FHIR in this space. We intend to continue to monitor and support advancements in the use of FHIR-based standards for cancer reporting and reflect such advancements in Certification Program requirements in the future as appropriate.

Comments. Many commenters stated that the proposed removal of the certification criterion in § 170.315(f)(4) would shift burden to providers and public health in a variety of ways. Commenters stated that removal of the certification criterion could result in increased variability, uneven implementations, bespoke interfaces, and a return to manual or non-standardized processes. Commenters stated that registries could be required to do more local specification, onboarding, testing, validation, and direct developer coordination as a result of removal of the certification criterion.

Response. We appreciate these comments regarding the potential for burden shifting due to the proposed removal of the certification criterion in § 170.315(f)(4). We have not finalized

the proposed removal of the certification criterion in § 170.315(f)(4) for the reasons noted in the response directly above.

Comments. Some commenters expressed concerns that the proposal could disrupt cancer reporting to a degree that it would negatively impact cancer care and research. Commenters stated that data quality, completeness, timeliness, continuity, and reliability could decline as a result of removal of the certification criterion in § 170.315(f)(4). Some commenters described cancer reporting as too important to risk such disruption and noted the importance of cancer reporting to surveillance, incidence tracking, research, disparities work, treatment evaluation, prevention, resource allocation, and public health investigations. Some commenters viewed certification to the certification criterion in § 170.315(f)(4) as an important safeguard or accountability mechanism to ensure against disruption in cancer reporting.

Response. We thank commenters for these comments expressing concern regarding a potential disruption of cancer reporting. We agree with comments regarding the importance of cancer reporting and its impact on cancer care and research. Given the value that commenters indicated certification continues to bring to this use case as well as the concerns raised by commenters regarding disruption of standardized reporting and interoperability, we have not finalized the proposed removal of the certification criterion in § 170.315(f)(4).

Comments. Some commenters expressed concerns that the proposal does not align with CMS program requirements. Some commenters noted that providers still rely on this functionality for the MIPS Promoting Interoperability performance category and related public health participation.

Response. We thank commenters for expressing these concerns about CMS alignment. We noted in the Proposed Rule that MIPS eligible clinicians that report on the Public Health Registry measure in the MIPS Promoting Interoperability performance category may earn optional bonus points for submitting data to cancer registries using health IT certified to the criterion in § 170.315(f)(4) (90 FR 60992). We have not finalized the proposed removal of the certification criterion in § 170.315(f)(4) and do not anticipate any issues regarding alignment with CMS program requirements.

Comments. Some commenters stated that the proposal relies on an incomplete understanding of the Helios

³⁹ <https://www.hhs.gov/press-room/hhs-crackdown-health-data-blocking.html>.

work. They stated that the Helios cancer work is about query/response or supplemental follow-up information and is not a replacement for initial cancer case reporting.

Response. We thank commenters for these comments. Commenters are correct that Helios has worked on query/response, but there are other HL7 initiatives and standards development work related to cancer reporting. ONC will continue to monitor progress on the FHIR-based Central Cancer Registry Reporting Content Implementation Guide, as well as the work related to USCDI+ Cancer⁴⁰ and their associated implementation guides. Specifically, USCDI+ Cancer has been working closely with the Central Cancer Registry Reporting Content Implementation Guide v2.0 to incorporate early incidence reporting from EHR data. This version was balloted in January 2026.

Comments. A few commenters stated that removing the certification criterion in § 170.315(f)(4) would weaken incentives for EHRs and developers to support interoperability.

Response. We thank commenters for expressing concerns about maintaining developer support for interoperability. We appreciate the important role of the Certification Program in improving interoperability and will continue to support that goal through Certification Program requirements. As stated above, we have not finalized the proposed removal of the certification criterion in § 170.315(f)(4), and we will continue to monitor industry progress to inform whether future rulemaking is needed to help ensure interoperability and effective reporting to cancer registries.

Comments. Several commenters stated that substantial investment has already been made in the current CDA standards-based infrastructure, and removal could undo harmonization progress.

Response. We thank commenters for these comments regarding the investments made to date in CDA-based standards for cancer reporting. We have not finalized the proposed removal of the certification criterion in § 170.315(f)(4), and we will continue to monitor industry progress towards FHIR-based standards for cancer reporting.

Comments. Several commenters expressed concerns about timelines and stated that developers, registries, public health agencies, and providers need more implementation time before

removal of the certification criterion in § 170.315(f)(4). Another commenter supported an effective date no earlier than January 1, 2029, for the removal of the CDA-based public health-related certification criteria and the adoption of FHIR-based approaches to reporting.

Response. We appreciate the concerns regarding timelines and the need for more implementation time prior to removal of the certification criterion in § 170.315(f)(4). We have not finalized the proposed removal of the certification criterion in § 170.315(f)(4).

Comments. Some commenters expressed support for removal of the criterion, stating that it could reduce burden, was appropriate given low adoption of the current criterion, and could allow developers to shift efforts toward FHIR-based reporting. A commenter stated that provider-based reporting for cancer is likely redundant because a mandate for laboratory reporting already exists under the Clinical Laboratory Improvement Amendments (CLIA).

Response. We thank commenters for these comments in support of our proposal. We agree with commenters regarding the importance of shifting toward FHIR-based reporting to cancer registries. While we have not finalized our proposal to remove this certification criterion at this time, we will continue to monitor advancements in FHIR-based cancer reporting.

Regarding the comment received regarding the redundancy of provider-based cancer reporting due to CLIA requirements, we note that the CLIA requirements in 42 CFR part 493 only require that a laboratory has “an adequate manual or electronic system(s) in place”⁴¹ to send test results accurately and reliably, and thus the standards-based certification requirements in § 170.315(f)(4) are not redundant. Further, CLIA covers pathology reporting and laboratories, and cancer registry reporting encompasses more than pathology and covers hospitals and providers, in addition to laboratories.

Comments. Several commenters identified issues that are out of scope, such as broader public health infrastructure funding and workforce readiness, contract language issues, the need to coordinate updates to State reporting laws, expanding Health IT certification requirements to public health systems, CDC’s Vocabulary Access and Distribution System, and coordination with other agencies to avoid misaligned incentives.

Response. We thank commenters for these comments. However, these comments were outside the scope of this rulemaking.

b. Transmission to Public Health Agencies—Electronic Case Reporting

We proposed to revise the “transmission to public health agencies—electronic case reporting” (eCR) certification criterion in § 170.315(f)(5). This criterion enables a user to create case reports that can be transmitted electronically to public health agencies. We proposed to revise the eCR certification criterion to be a functional requirement in order to reduce burden and allow for industry innovation. In particular, we proposed to rescind the expiration date for the functional requirements defined in § 170.315(f)(5) as of the effective date of this final rule. We proposed to revise the introductory text of the criterion to enable a user to create a case report for electronic transmission meeting the functional requirements described in paragraph (f)(5)(i) of this section. Additionally, we proposed to remove the standards-based requirements defined in § 170.315(f)(5)(ii) as of the effective date of this final rule and to reserve that section.

Comments. The vast majority of comments, including those from health care providers, developers and public health, were not supportive of revising the eCR certification criterion to remove standards-based requirements and rely on a functional-only approach, primarily due to concerns that FHIR-based standards for eCR are still maturing and not ready as a replacement for CDA-based standards. Several commenters also stressed that many receiving public health systems were not ready for FHIR-based reporting. Some commenters recommended retaining flexibility for either CDA-based or FHIR-based standards for eCR in the short-term and moving exclusively to FHIR-based requirements only after the FHIR standard fully matures and there is sufficient implementation time to ensure that the CDC, Public Health Authorities (PHAs), and physicians have the technology and standards in place to transition to FHIR. Some commenters stressed that the current requirement provides an opportunity to use CDA-based or FHIR-based standards and to migrate as needed, thus serving as a clear glidepath to FHIR-based standards and enabling progress toward exclusively FHIR-based eCR in the future. Many commenters indicated support for FHIR-based eCR in the future but expressed concerns that

⁴⁰ For more information about USCDI+ Cancer, see https://uscdiplus.healthit.gov/uscdiplus?id=uscdi_record&table=x_g_sshh_uscdi_domain&sys_id=71df78228745b95098e5edb90cbb3527&view=sp.

⁴¹ 42 CFR 493.1291(a).

revising the eCR certification criterion to remove standards-based requirements prior to a FHIR-based standard being widely available would increase variability in implementations, shift burden to providers and public health agencies, and reduce the timeliness, completeness, and reliability of public health reporting.

Response. We thank commenters for expressing these concerns regarding revising the eCR certification criterion in § 170.315(f)(5) to be a functional requirement prior to having a mature FHIR-based standard widely available. We recognize that there is still a significant amount of reliance on CDA-based standards for eCR as well as limited adoption of FHIR-based standards for eCR on both the sending and receiving ends of transactions. Having considered the points raised by commenters, we have decided not to finalize the proposal to revise the certification criterion in § 170.315(f)(5) to be a functional requirement. However, we also have confidence in the future progression of FHIR in this space and agree with commenters that retaining the ability to certify to either CDA-based standards or FHIR-based standards for eCR in the meantime can provide a helpful glidepath and encourage progress toward a fully FHIR-based future.

Comments. A number of commenters expressed concerns about removing standards in the eCR criterion and making it a functional criterion. Several commenters stressed that a functional-only approach would undermine interoperability, consistency, and predictability. Some stressed that the shift to functional requirements could degrade data quality, integrity, completeness, timeliness, reliability, usability, and comparability. Some commenters stated that a functional requirement could result in increased integration burdens on downstream systems such as public health agencies. Some commenters stated that the proposal would disrupt significant progress that has been made through standards-based eCR adoption. These commenters stated that standards-based eCR adoption has steadily increased and has reduced burden on both public health and healthcare organizations to meet reporting requirements. Another commenter stated that removal of standards-based requirements may result in fragmented and jurisdiction-specific reporting. Some commenters stressed that standards are needed to prevent inconsistencies and variability that would undermine public health efforts, including outbreak response and real-time surveillance, and require

burdensome workarounds. Several commenters noted specific benefits of the eCR criterion, including detecting and responding to communicable diseases impacting the population. Another commenter stated that having the eCR criterion as part of CEHRT has been vital to advancing eCR and that if it becomes a functional requirement only, PHAs would have the burden of processing non-standardized formats and providers may revert to fax-based reporting, eroding efficiency and reversing progress.

Response. We appreciate the concerns expressed by commenters regarding removal of standards in the eCR criterion and instead relying on functional requirements, including concerns that it would result in fragmentation and variability that would impede public health efforts and increase burden. While functional requirements are appropriate in some instances, we recognize that may not be the case where there is ongoing modernization of standards. We agree with commenters that the current criterion requirements, which allow the use of either CDA-based standards or FHIR-based standards for eCR, have been successful in moving eCR forward to date and that retaining them for the time being can help ensure continued progress. We have not finalized the proposal to revise the certification criterion in § 170.315(f)(5) to be a functional requirement. We will continue to monitor advancements in the use of FHIR-based standards for eCR.

Comments. A number of commenters expressed concerns that the proposal would reduce public health situational awareness, create public health operations issues, and weaken emergency preparedness, including disease surveillance and outbreak detection and response.

Response. We thank commenters for expressing these concerns, and we understand the importance of not impeding vital public health operations. We have not finalized the proposal to revise the certification criterion in § 170.315(f)(5) to be a functional requirement.

Comments. A number of commenters expressed concern about burden. Some commenters stated that burden would move from certification and developers to providers, public health agencies, and governments. Some commenters stressed that small, rural and under-resourced providers would be particularly impacted by increased burden. In addition, some commenters stated that public health agencies lacked the infrastructure, workforce, funding,

or governance capacity to transition to FHIR. Some commenters stated that the proposal will shift the burden of assessing health IT functionality and standards adoption away from ONC to the users of health IT, imposing additional burden on individuals, governments, and healthcare organizations as they evaluate and select health IT to purchase and implement. Several commenters characterized the proposal as an unfunded mandate.

Response. We appreciate these commenter concerns regarding burden. We understand that for many under-resourced settings moving toward FHIR-based standards for eCR could be burdensome. We have not finalized the proposal to revise the certification criterion in § 170.315(f)(5) to be a functional requirement and are retaining the current criterion requirements, which require the use of either CDA-based standards or FHIR-based standards for certification to the eCR criterion. This addresses commenter concerns about burden and, as stated above, provides a helpful glidepath toward more ubiquitous FHIR-based eCR in the future.

Comments. Several commenters stated that developers who already invested in the current standards-based options in § 170.315(f)(5)(ii) would be penalized. Another commenter was concerned that all developers were required to comply with paragraph § 170.315(f)(5)(ii) by February 28, 2026, and that developers would now be required to revert back to meeting the requirements of § 170.315(f)(5)(i). They noted that paragraph § 170.315(f)(5)(i) specifically refers to standards in § 170.213, § 170.207(i), and § 170.207(a)(1) and that reverting back to § 170.315(f)(5)(i) would create additional burden for developers by requiring them to ensure their product meets those requirements and to attest to paragraph § 170.315(f)(5)(i) again.

Response. We thank the commenter for raising this concern. We have not finalized the proposal to revise the certification criterion in § 170.315(f)(5) to be a functional requirement and have retained the current criterion requirements. Additionally, we recognize and appreciate the efforts of developers who have certified to the requirements in § 170.315(f)(5)(ii).

Comments. Several commenters recommended extending expiration dates, generally recommending establishing an expiration date for CDA-based eCR no later than December 31, 2028, and for full FHIR-based implementation of eCR by January 1, 2029.

Response. We thank commenters for these comments. We have not finalized the proposal to revise the certification criterion in § 170.315(f)(5) to be a functional requirement.

Comments. Several commenters expressed concerns about aligning with CMS programs.

Response. We appreciate these concerns regarding alignment with CMS programs. We note that the certification criterion in § 170.315(f)(5) is currently required to complete the Electronic Case Reporting measure in the CMS MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.⁴² In 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” final rule (CY 2026 PFS final rule), CMS finalized a policy to suppress the measure for performance for MIPS eligible clinicians meeting the requirements of the MIPS Promoting Interoperability performance category for the CY 2025 performance period and for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025 (90 FR 49892). As there is no change to the availability of the certification criterion in § 170.315(f)(5) under this final rule, there is no related impact to current CMS requirements with respect to certified functionality for the Electronic Case Reporting measure.

Comments. Comments in support of the proposal stated it would reduce unnecessary standards-specific burden, avoid prescribing standards before the public health sector is ready, and allow continued use of existing operational exchange pathways.

Response. We thank commenters for these comments in support of our proposal. We understand the importance of reducing unnecessary burden on developers of certified health IT as well as the need to avoid requiring standards before the public health sector is ready. Due to commenter concerns regarding the potential standards-conformance and interoperability impact of moving to a functional approach, we have retained the current criterion requirements which requires the use of either CDA-based standards or FHIR-based standards for certification

to the eCR criterion. We believe this will help provide a glidepath toward more universal adoption of FHIR-based eCR in the future.

Comments. Several commenters identified issues that were out of scope for our proposal. These included comments regarding the enforcement discretion, adoption of newer standards, broader public health infrastructure funding, incentives for adoption, CDC’s Vocabulary Access and Distribution System, trigger standardization, alternative oversight or accountability mechanisms outside certification, and finalizing our proposals in HTI-2.

Response. We thank commenters for these comments; however, these comments were outside the scope of this rulemaking.

c. Transmission to Public Health Agencies—Antimicrobial Use and Resistance Reporting

We proposed to revise the “transmission to public health agencies—antimicrobial use and resistance reporting” certification criterion in § 170.315(f)(6). This criterion assesses whether Health IT Modules can create and properly format an antimicrobial use and resistance report for electronic transmission, following specified sections of a CDA-based implementation guide. We proposed to revise the criterion requirements to be functional only and proposed to remove the reference to the standard in § 170.205(r)(1) as of the effective date of this final rule.

Comments. The majority of commenters were not supportive of revising the transmission to public health agencies—antimicrobial use and resistance reporting certification criterion in § 170.315(f)(6) to remove referenced standards and rely on a functional requirement, often due to concerns that FHIR was not fully mature or widely adopted. Several commenters stated that receiving public health agencies were not ready for full FHIR-based reporting, and some stated that the existing CDA-based standards for reporting to public health have been adopted in a number of settings and are important for continuity. Some commenters expressed concerns about timing due to lack of FHIR readiness and did not support revising the certification criterion in § 170.315(f)(6) to remove the referenced CDA-based standard until a FHIR-based replacement was operationally ready. Another commenter supported an effective date no earlier than January 1, 2029, for any changes to the certification criterion in § 170.315(f)(6) and for removal of the CDA-based public

health-related certification criteria and adoption of FHIR-based approaches to reporting. Commenters had concerns that without a FHIR-based replacement available, removal of the referenced standard in § 170.315(f)(6) would reduce standardization, increase variability, shift burden and costs to providers and public health agencies, and disrupt public health reporting and surveillance.

Response. We thank commenters for expressing these concerns regarding FHIR readiness and removing the CDA-based standards from the certification criterion in § 170.315(f)(6). We recognize that for certain public health use cases CDA-based standards are widely used for public health reporting and FHIR-based standards are still in development. However, antimicrobial use and resistance reporting is made to the CDC’s National Healthcare Safety Network (NHSN), and the CDA-based standard referenced in § 170.315(f)(6) is currently not aligned with NHSN requirements. Additional rulemaking to address this misalignment would likely require several years to complete, and we believe that lack of alignment with NHSN requirements will undermine the effectiveness of the certification criterion in § 170.315(f)(6) until such steps can be completed. As we noted in the Proposed Rule, the CDC is working to move reporting to FHIR-based standards⁴³ and has already implemented a more recent version of the CDA-IG. Further, we identified trends within the industry regarding a shift in reporting approach that supports revision of this criterion (90 FR 60993).⁴⁴ Revising the certification criterion in § 170.315(f)(6) to include a functional requirement rather than a mis-aligned CDA-based requirement ensures that antimicrobial use and resistance reporting capabilities are still included in certified health IT while also allowing developers of certified health IT to better align with, and advance alongside, NHSN requirements at this time. Accordingly, we have adopted our revisions as proposed. We will continue to monitor the development of FHIR-based standards in this area as they mature.

Comments. Several commenters expressed concerns about burden, including increasing manual reporting burden on providers and registries. Commenters expressed concern that the

⁴² See the CY 2026 PFS Proposed Rule Table 62, available at <https://www.federalregister.gov/d/2025-13271/p-3055> and the FY2026 IPPS/LTCH PPS Final Rule Table X.F.—05 available at <https://www.federalregister.gov/d/2025-14681/p-4161>.

⁴³ For information on CDC’s National Healthcare Safety Network (NHSN) antimicrobial use and resistance reporting options see <https://www.cdc.gov/nhsn/psc/aur/index.html>.

⁴⁴ <https://stacks.cdc.gov/view/cdc/118849#:~:text=July%2027%2C%202021,2021%20Export%20RIS%20Citation%20Information>.

proposal would result in increased variability and significant integration work for health IT developers, healthcare organizations, and public health agencies, as well as increased burden around selecting health IT. Some commenters expressed concern that significant costs would shift to providers and public health.

Response. We appreciate concerns regarding increased costs and burdens for providers, public health, and health IT developers. We understand the importance of ensuring interoperability and reducing variability in public health reporting. However, the current standard in § 170.315(f)(6) is misaligned, and including, as we have finalized, a functional requirement in § 170.315(f)(6) instead will allow for better alignment with NHSN reporting requirements while still ensuring that certified health IT has antimicrobial use and resistance reporting capabilities.

Comments. Several commenters expressed concern about alignment with CMS requirements.

Response. We thank commenters for these comments regarding CMS alignment. We noted in the Proposed Rule that the certification criterion in § 170.315(f)(6) is required for completing the Antimicrobial Use Surveillance and Antimicrobial Resistance Surveillance measures in the Medicare Promoting Interoperability Program for eligible hospitals and CAHs (90 FR 60993). We did not propose to remove the certification criterion in § 170.315(f)(6), and even though we have revised it to include functional requirements only, we do not anticipate any alignment issues with CMS requirements, as eligible hospitals and CAHs would continue to use EHR technology certified to the criterion when reporting the measure.

Comments. Several commenters expressed concerns about replacing the current standards-based requirements with functional requirements. Some commenters stated that functional requirements could undermine interoperability, consistency, and predictability. Another commenter recommended listing multiple standards instead of having a functional requirement.

Response. We appreciate commenter concerns regarding issues with functional requirements. We understand the importance of ensuring interoperability and consistency in public health reporting. However, the current standard in § 170.315(f)(6) is misaligned with NHSN reporting requirements, and including a functional requirement in § 170.315(f)(6) instead will allow for better alignment

with NHSN reporting requirements while still ensuring that certified health IT has antimicrobial use and resistance reporting capabilities.

Comments. Several commenters requested that ONC provide a clearer transition path toward FHIR-based reporting, and another commenter who supported the proposal suggested ongoing monitoring and implementation guardrails as reporting transitions from the C-CDA standards required in the criterion.

Response. We appreciate these comments regarding a transition path toward FHIR-based reporting. As noted above, the CDC is working to move reporting to FHIR-based standards, and revising the certification criterion in § 170.315(f)(6) as proposed to include a functional requirement will allow developers of certified health IT to move to FHIR-based standards as those standards mature. Further, the functional criterion will allow developers to use the most recent version of the CDA IG as the FHIR transition occurs. As discussed above, there is current misalignment, even with SVAP, between the certification criterion's standard and NHSN. The shift to a functional criterion will allow for faster implementation of standards advancement and remove the current issue with misalignment between Federal programs. We encourage that transition to FHIR-based standards and note that we will continue to provide resources and guidance regarding movement toward FHIR-based standards on our website.

Comments. Commenters in support of the proposal stated that it would reduce the burden of maintaining duplicative standards and better align certification with NHSN reporting requirements. They stated that because AUR reporting is exclusively directed to the NHSN, which has its own separate standards and validation process, the current certification requirement is duplicative. Some commenters stated that the criterion was poorly adopted.

Response. We thank commenters for their comments in support of our proposal. We agree with commenters that the current standard in § 170.315(f)(6) is misaligned with NHSN reporting requirements and creates burden for developers of certified health IT. We have finalized the proposal as proposed.

Comments. Several commenters identified issues that were out of scope for our proposal. These included comments regarding penicillin allergy de-labeling, preferred terminology choices, laboratory order and result standards, contracting language for

public health exchange, withdrawn proposals from HTI-2, and incentives for FHIR adoption.

Response. We thank commenters for these comments. However, these comments were outside the scope of this rulemaking. We have finalized the proposal as proposed.

d. Transmission to Public Health Agencies—Health Care Surveys

We proposed to remove the “transmission to public health agencies—health care surveys” certification criterion in § 170.315(f)(7). This criterion supports the transmission of health care surveys directly to the CDC. We stated that removing the certification criterion in § 170.315(f)(7) would reduce burden while at the same time honoring our policy goals to ensure health IT interoperability and functionality (90 FR 60994). We also stated that removal would encourage industry to modernize reporting approaches alongside CDC's efforts (90 FR 60994). We proposed a January 1, 2027, effective date for the removal of the transmission to public health agencies—health care surveys criterion in § 170.315(f)(7).

Comments. The majority of commenters were not supportive of our proposal to remove the transmission to public health agencies—health care surveys certification criterion in § 170.315(f)(7), primarily due to concerns that FHIR-based standards are not mature enough and receiving public health systems are not ready for FHIR-based reporting. While commenters often expressed support for FHIR-based public health reporting in the future, many commenters stated that readiness, implementation, scalability, maintenance, and receiving-system capacity for FHIR-based public health reporting are not yet sufficient. Several commenters stated that immediate removal of the certification criterion in § 170.315(f)(7) is not appropriate without a future FHIR path, or other alternative, in place before removal. Commenters expressed concerns that without a replacement, removal of the certification criterion in § 170.315(f)(7) would weaken established reporting capabilities, reduce standardization, increase manual processes or burden, and disrupt data used for public health planning, surveillance, and quality reporting. Some commenters recommended retaining the criterion until January 1, 2029. A few commenters recommended a short-term functional requirement, paired with clear milestones toward broader FHIR adoption, although several other commenters expressed opposition to a

functional requirement. Another commenter recommended adding a FHIR-based standard to the requirements in § 170.315(f)(7) in addition to the current CDA-based standard. Some commenters recommended that ONC establish a clear transition path to FHIR-based reporting, with guidance on retaining CDA-based capabilities during transition and alternative accountability mechanisms.

Response. We appreciate these concerns regarding FHIR-readiness and perceived premature removal of the certification criterion in § 170.315(f)(7). We understand that currently CDA-based standards are used in a number of settings for public health reporting. After considering the concerns expressed by commenters, we have decided not to finalize the proposal to remove the certification criterion in § 170.315(f)(7). However, we also agree with comments expressing support for movement toward FHIR-based reporting in the future, and we anticipate significant advancements toward FHIR in this space. In the Proposed Rule, we noted CDC priorities around data modernization and encouraging the use of FHIR-based approaches for public health reporting (90 FR 60994). We intend to continue to monitor and support the progression of FHIR-based standards for health care surveys.

Comments. Several commenters expressed concern that the proposal would disrupt recent progress in standardizing public health reporting. Some commenters stated that public health reporting has made meaningful progress through standards-based exchange and that removal of this criterion could reverse that progress. Several commenters stated that moving away from standards-based certification could increase variability, fragmentation, and uneven implementation.

Response. We appreciate these comments regarding the recent progress in standardizing public health reporting, and we understand the importance of ensuring continued participation in, and reporting of, health care surveys. We have not finalized the proposed removal of the certification criterion in § 170.315(f)(7), but we will continue to monitor and support the progression of FHIR-based standards for healthcare reporting.

Comments. A number of commenters expressed concern about burden. Some commenters stated that the proposal could shift burden and costs downstream to providers and public health agencies. Commenters stated that removal of the certification requirement

could result in burden for providers and PHAs regarding tracking, custom integration, manual work, and other operational issues. Some commenters stated that burden on health IT developers, healthcare organizations and public health agencies could increase because removal of standards-based transmission requirements may result in increased variability and capabilities in EHR systems. Another commenter stressed that while removal may allow room for industry innovation, public health would not have the resources to actually innovate.

Response. We appreciate these comments regarding the potential for burden shifting due to the proposed removal of the certification criterion in § 170.315(f)(7). We acknowledge that commenters identified burden-reduction benefits related to certification to this criterion. We have not finalized the proposed removal of the certification criterion in § 170.315(f)(7).

Comments. Several commenters expressed concerns that new certified products might no longer support survey submission if the criterion is removed and that this would harm the reporting ecosystem. Some commenters stated that vendor investment and maintenance could erode without the certification requirement in place and that the resulting degradation in CDA document exchange could disrupt public health reporting. Another commenter recommended that where certification requirements are removed, ONC should take steps to prevent these functions from becoming optional vendor add-ons and prevent shifting disproportionate burden onto provider organizations.

Response. We thank commenters for expressing these concerns regarding a potential lack of support for health care surveys in certified health IT as a result of the proposed removal of the certification criterion in § 170.315(f)(7). We have not finalized the proposed removal of the certification criterion in § 170.315(f)(7).

Comments. Several commenters questioned the burden-reduction rationale for the proposal. They stated that the current capability is already well established and retaining it would not impose meaningful additional burden.

Response. We thank commenters for their comments regarding burden reduction. We appreciate that for well-established functionality there may not be significant burden related to maintaining the certification criterion in § 170.315(f)(7), however we note that

there would still be burden related to certifying to this criterion.

Comments. Some commenters expressed support for our proposal to remove the certification criterion in § 170.315(f)(7). Commenters stated that the proposal would reduce burden where survey submission is infrequent or lacks a clear, consistent submission pathway. Another commenter stated that providers are rarely asked to submit data and that significant development investment has yielded minimal public health benefits.

Response. We thank commenters for these comments in support of our proposal. We understand the importance of reducing burden on developers of certified health IT as well as the need to ensure that burden reduction does not negatively impact core Certification Program policy priorities around interoperability. We have not finalized the proposed removal of the certification criterion in § 170.315(f)(7).

Comments. Several comments were out of scope. These included comments regarding Certification Program oversight, redundant requirements, Conditions of Participation alignment, enhanced real-world testing, testing tools, third-party testing, and structured attestation.

Response. We thank commenters for these comments. However, these comments were outside the scope of this rulemaking.

7. Design and Performance Certification Criteria

a. Automated Numerator Recording

As discussed in the Proposed Rule, the certification criterion in § 170.315(g)(1) requires the capability to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the numerator of a percentage-based measure in the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program (90 FR 60994).

In the Proposed Rule, we proposed to remove the “automated numerator recording” certification criterion and reserve § 170.315(g)(1) with an effective date of January 1, 2027. We stated in the Proposed Rule that we reviewed and evaluated the certification criterion in § 170.315(g)(1), seeking to identify ways to reduce burden while still supporting our policy goals. We explained that we believe that developers now have significant experience with implementing CMS measure requirements in the Promoting

Interoperability programs, and they will continue to ensure that the measures are recorded in a fashion that meets CMS requirements to ensure that their customers can successfully participate in the absence of additional testing requirements under the Certification Program. (90 FR 60994).

Comments. We received a number of comments that expressed concern that the removal of § 170.315(g)(1) would reduce reliable and transparent assurance of accurate calculation for Health IT Modules. These commenters stated that without the certification criterion in § 170.315(g)(1), customers would not have assurance that the metrics for Health IT Modules are accurate. Some commenters suggested that the removal of § 170.315(g)(1) would shift burden to health care providers who would need to conduct their own testing to verify the metrics for Health IT Modules. Several commenters also asserted that new health IT developers may not conform to the standard without the requirement of certifying to § 170.315(g)(1) affecting the functionality of Health IT Modules.

Response. We appreciate commenters' concerns about the lack of assurance of accurate calculation for measures in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category if § 170.315(g)(1) is removed. We note that developers now have more time and experience with CMS programs than when this certification criterion was first adopted. We believe that health IT developers will continue to ensure that patients or actions included in a measure's numerator are recorded in a fashion that supports accurate calculation to meet CMS requirements without needing to certify to § 170.315(g)(1). We further note that CMS has previously clarified, under the EHR Incentive Programs which preceded the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category, that while CEHRT must include this capability, program participants may use a separate, non-certified system to calculate numerators and denominators and to generate reports on the measures.⁴⁵

Comments. We received a number of comments that expressed concern that the removal of § 170.315(g)(1) would create a lack of alignment with the requirements that CMS maintains in the Medicare Promoting Interoperability Program and MIPS Promoting

Interoperability performance category. Some commenters questioned if the removal of § 170.315(g)(1) would reduce burden for health IT developers if CMS maintains its requirements in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. Many commenters requested that we work with CMS to provide clear guidance and address alignment issues regarding the transition to remove § 170.315(g)(1). Several commenters also suggested that we delay the removal of § 170.315(g)(1) to allow time to address CMS alignment with the removal of the certification criterion.

Response. We appreciate the comments about alignment with the requirements in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. In the FY 2027 IPPS/LTCH PPS proposed rule, we note that CMS proposed to remove the cross-reference to § 170.315(g)(1) in 42 CFR 495.4, which is applicable to the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, effective January 1, 2027 (91 FR 19620). CMS finalized this proposal in the FY 2027 IPPS/LTCH PPS final rule which appeared in the **Federal Register** on August 4, 2026 (91 FR 50033). CMS has made a similar proposal with respect to the MIPS Promoting Interoperability category in the CY 2027 PFS proposed rule (91 FR 44170). We believe that CMS' final and proposed revisions to the definition of CEHRT in 42 CFR 495.4 and 42 CFR 414.1305 allow for alignment with our timeline for the removal of the certification criterion in § 170.315(g)(1). We will continue to coordinate with CMS as it seeks to implement and finalize these proposals.

We also noted in the Proposed Rule that if we ultimately finalized the removal of § 170.315(g)(1), we would work with CMS to ensure relevant guidance and materials for existing measures are consolidated as part of the informational materials that CMS maintains regarding measures in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category (90 FR 60994). We believe that this coordination will minimize any burden for program participants.

Comments. We received a number of comments that expressed support for our proposal to remove the certification criterion. These commenters stated that the removal of § 170.315(g)(1) would reduce burden from testing to certify to the certification criterion for health IT developers because the testing requirements for certification to

§ 170.315(g)(1) were difficult to assess and burdensome to conduct for health IT developers. Another commenter also asserted that the numerator/denominator measurement model supported by the certification criterion in § 170.315(g)(1) is obsolete in the current health IT industry.

Response. We appreciate the comments we received about the burden. We have finalized the removal of § 170.315(g)(1) with an effective date of January 1, 2027, as proposed. We look forward to ongoing collaboration with public and private sector partners as we implement the provisions of this final rule.

b. Automated Measure Calculation

As discussed in the Proposed Rule, the certification criterion in § 170.315(g)(2) requires the capability to record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable measure in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (90 FR 60994).

In the Proposed Rule, we proposed to remove the "automated measure calculation" certification criterion and reserve § 170.315(g)(2) with an effective date of January 1, 2027. We explained in the Proposed Rule that we reviewed and evaluated the certification criterion in § 170.315(g)(2), seeking to identify ways to reduce burden while still supporting our policy goals. As with the automated numerator recording certification criterion discussed above, health IT developers that facilitate customer participation in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category have been supporting the calculation of measures in the program and its previous iterations for many years. We explained that we believe that developers now have significant experience with implementing the CMS measure requirements, and that they will continue to ensure that the measures are calculated in a fashion that meets CMS requirements to ensure that their customers can successfully participate in these programs in the absence of additional testing requirements under the Certification Program (90 FR 60995).

Comments. We received a number of comments that expressed concern that the removal of § 170.315(g)(2) would reduce reliable and transparent assurance of accurate calculation for Health IT Modules. These commenters stated that without the certification criterion in § 170.315(g)(2), customers

⁴⁵ See https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/FAQ_CEHRT.pdf.

would not have assurance that the metrics for Health IT Modules are accurate. Some commenters suggested that the removal of § 170.315(g)(2) would shift burden to health care providers who would need to conduct their own testing to verify the metrics for Health IT Modules. Several commenters also asserted that new health IT developers may not conform to the standard without the requirement of certifying to § 170.315(g)(2) affecting the functionality of Health IT Modules.

Response. We appreciate commenters' concerns about the lack of assurance of accurate calculation for measures in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category if § 170.315(g)(2) is removed. We note that developers now have more time and experience with CMS programs than when this certification criterion was first adopted. We believe that health IT developers will continue to ensure that Health IT Modules provide the capability to record the numerator and denominator and to create a report including the numerator, denominator, and resulting percentage in a fashion that supports accurate calculation to meet CMS requirements without needing to certify to § 170.315(g)(2). We further note that CMS has previously clarified that its programs do not specify that this capability must be used to calculate numerators and denominators for the measures. Eligible clinicians, eligible hospitals, and CAHs, may currently use a separate, non-certified system to calculate numerators and denominators and to generate reports on the measures.⁴⁶

Comments. We received a number of comments that expressed concern that the removal of § 170.315(g)(2) would create a lack of alignment with the requirements that CMS maintains in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. Some commenters questioned if the removal of § 170.315(g)(2) would reduce burden for health IT developers if CMS maintains its requirements in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. Many commenters requested that we work with CMS to provide clear guidance and address alignment issues regarding the transition to remove § 170.315(g)(2). Several commenters also suggested that we delay the removal of § 170.315(g)(2) to allow time to address

CMS alignment with the removal of the certification criterion.

Response. We appreciate the comments about alignment with the requirements in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. In the FY 2027 IPPS/LTCH PPS proposed rule, we note that CMS proposed to remove the cross-reference to § 170.315(g)(2) in 42 CFR 495.4, which is applicable to the Medicare Promoting Interoperability Program for eligible hospitals and CAHs, effective January 1, 2027 (91 FR 19620). CMS subsequently finalized this proposal in the FY 2027 IPPS/LTCH PPS final rule which appeared in the **Federal Register** on August 4, 2026 (91 FR 50033). CMS has made similar proposals with respect to the MIPS Promoting Interoperability category (91 FR 44170). We believe that CMS' final and proposed revisions to the definition of CEHRT in 42 CFR 495.4 and 42 CFR 414.1305 allow for alignment with our timeline for the removal of the certification criterion in § 170.315(g)(2). We will continue to coordinate with CMS as they seek to implement and finalize these proposals.

We also noted in the Proposed Rule that if we ultimately finalized the removal of § 170.315(g)(2), we would work with CMS to ensure relevant guidance and materials for existing measures are consolidated as part of the informational materials that CMS maintains regarding measures in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category (90 FR 60994). We believe that this coordination will minimize any burden for program participants.

Comments. We received a number of comments that expressed support for our proposal to remove the certification criterion. These commenters stated that removing § 170.315(g)(2) would reduce burden from testing to certify to the criterion for health IT developers because the testing requirements for certification to § 170.315(g)(2) were difficult to assess and burdensome to conduct for health IT developers. Another commenter also asserted that the numerator/denominator measurement model supported by the certification criterion in § 170.315(g)(2) is obsolete in the current health IT industry.

Response. We appreciate the comments about the burden. We have finalized the removal of § 170.315(g)(2) with an effective date of January 1, 2027, as proposed. We look forward to ongoing collaboration with public and private sector partners as we implement the provisions of this final rule.

c. Safety-Enhanced Design

In the Proposed Rule (90 FR 60995), we proposed to remove the "safety-enhanced design" (SED) certification criterion in § 170.315(g)(3) and the reference to this certification criterion in § 170.550(g)(1) as of the effective date of this final rule. The safety-enhanced design certification criterion specifies the user-centered design testing that must be applied to certain health IT capabilities submitted for certification. Certification to this certification criterion is conditional as its scope and applicability depends on the other certification criteria for which a Health IT Module is presented for certification.

As discussed in the Proposed Rule (90 FR 60995 and 60996), we anticipated that removal of this certification criterion would reduce costs and burden for health IT developers and health care providers.

Comments. The majority of commenters were not supportive of removing the SED certification criterion in § 170.315(g)(3). These commenters stated that the SED certification criterion remains an important patient safety, usability, and human factors engineering safeguard and expressed concerns that removal of this certification criterion would weaken a baseline certification expectation for user-centered design, increase the risk of technology-induced errors, promote inefficiency and inconsistency, and shift responsibility for identifying and mitigating such risks to providers and purchasers. Some commenters noted that if safety verification became the responsibility of providers and purchasers, then smaller, rural, or low-resource practices would incur the most burden, as they may have limited technical resources and expertise to independently evaluate the safety and security of their software systems.

A few commenters who opposed removal of the SED certification criterion expressed concerns that removal may cause health IT developers to revert to engineering-centric interfaces or reduce incentives to prioritize the clinician-user experience and could create a scenario where provider organizations are charged for design techniques that were previously included in health IT products. A few other commenters stated that removal of § 170.315(g)(3) could create an unlevel playing field between established developers and new market entrants, particularly if new entrants are not held to comparable usability and safety expectations. Some commenters who opposed removal also noted that safety-enhanced design and usability testing

⁴⁶ See https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/FAQ_CEHRT.pdf.

may become more important as SI-enabled functionality is incorporated into certified health IT and recommended that safety validation approaches evolve rather than be eliminated.

Some of the commenters who recommended retaining the certification criterion emphasized that the SED certification criterion, and related usability requirements, were originally implemented in response to real-world patient safety incidents and that the certification criterion continues to serve as an important safeguard against technology-induced harm. Another commenter expressed concerns that removal without first putting critical safeguards in place could result in unsafe practices and billing fraud.

Response. We thank commenters for their feedback. We have not finalized our proposal to remove the SED certification criterion in § 170.315(g)(3) or the reference to this certification criterion in § 170.550(g)(1). Instead, we have finalized § 170.315(g)(3) with revisions, as of the effective date of this final rule. Specifically, we have finalized the revision of § 170.315(g)(3) to an attestation-based certification requirement by removing the requirements in § 170.315(g)(3)(ii), (iv), and (v), making conforming revisions to paragraph (g)(3), and retaining the reference to § 170.315(g)(3) in § 170.550(g)(1).

We acknowledge comments that recommended we retain § 170.315(g)(3) and stated that removal of the SED certification criterion would not be appropriate without a clearly defined replacement mechanism that preserves baseline expectations for user-centered design and safety validation. We also recognize commenters' statements that the SED certification criterion, and related usability requirements, were implemented in response to real-world patient safety incidents and that the certification criterion continues to serve as an important safeguard against technology-induced harm. We agree with these commenters that § 170.315(g)(3) continues to serve an important safety function in the Certification Program by maintaining baseline assurance that developers of certified health IT apply user-centered design processes to certain health IT capabilities.

In the Proposed Rule (90 FR 60995), we proposed to remove the SED certification criterion to reduce costs and burden associated with certification for health IT developers and health care providers. Specifically, we identified the testing and reporting requirements associated with certification to

§ 170.315(g)(3) as contributing to health IT developers' burden and stated that removal of the SED certification criterion could allow health IT developers to redirect time and resources toward more innovative approaches to support and improve safety-enhanced design in their products (90 FR 60996). In consideration of commenters' explanations for why we should retain the SED certification criterion, we reassessed whether our proposal to completely remove the criterion is necessary to achieve our objective of reducing costs and burden. We determined that revising § 170.315(g)(3) to establish an attestation-based certification requirement addresses these considerations by reducing the testing and reporting requirements associated with certification while retaining the certification expectation for the application of user-centered design practices to certain certified health IT capabilities.

Comments. Some commenters recommended that if the SED certification criterion was removed, we should adopt alternative mechanisms to support continued usability and safety oversight. A commenter suggested prioritizing the use of post-market data to identify usability failures. A few other commenters recommended that we provide explicit transition guidance for products currently certified to § 170.315(g)(3) to ensure continuity of safety expectations and avoid gaps during any transition. Another commenter recommended that we provide a model risk assessment framework, particularly tailored to rural and low-resource providers, to support evaluation of health IT usability and safety in the absence of this certification requirement.

Response. We acknowledge commenters who recommended alternatives to our proposal, including prioritizing the use of post-market data to identify usability failures, providing explicit transition guidance, and offering additional tools to support providers in evaluating usability and safety. While we have not adopted these suggested alternatives in this final rule, the revisions that we have finalized to § 170.315(g)(3) take into consideration comments that urged us to continue to support usability and safety oversight certification requirements rather than eliminate them completely.

Comments. A smaller number of commenters expressed support for removing or streamlining the SED certification criterion. Of the commenters who supported removal of § 170.315(g)(3), most stated that current

summative usability testing and related documentation requirements are costly and administratively burdensome, have limited practical value, and divert resources from formative usability testing and other product improvement activities. Additionally, commenters who supported removal of this certification criterion agreed that there is widespread market adoption of safety-enhanced design practices. Other commenters recommended that, rather than remove the certification criterion, we should retain and modernize or streamline it. These recommendations included adopting a lean form of SED by narrowing requirements, focusing on higher-risk workflows, adopting a lighter-weight attestation-based approach, reducing prescriptive reporting, and aligning with recognized usability engineering frameworks such as those defined by the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO). Many of these commenters stated that formative usability testing conducted during development is more effective than the required summative testing model and that removing the current certification requirements would allow resources to be redirected toward more impactful usability practices. Another commenter specified that conducting user-centered design testing after development practices limits the ability to incorporate findings into products and that clients rarely access or use the detailed reports required by the SED certification criterion. Another commenter stated that safety-enhanced design features should be decided by markets.

Response. We thank commenters for their feedback and perspectives on how safety-enhanced design continues to play an important role in supporting safe and effective use of certified health IT but that current summative usability testing and related documentation requirements are costly and administratively burdensome. As discussed above, we have finalized revisions to § 170.315(g)(3) that reduce prescriptive testing and reporting requirements while retaining a meaningful certification expectation for user-centered design. This approach is intended to balance the need to maintain baseline safety and usability expectations with the goal of reducing unnecessary burden and allowing health IT developers to redirect time and resources towards more innovative approaches to support and improve safety-enhanced design in their products. We refer readers to section VII

(Regulatory Impact Analysis) of this final rule for more detailed information on cost estimates of safety-enhanced design and estimated cost savings.

We have determined that the current reporting requirements for the SED certification criterion can be reduced to an attestation-based approach that retains a meaningful certification expectation for SED. Therefore, we have finalized the SED certification criterion in § 170.315(g)(3) to an attestation-based certification requirement by removing the requirements in § 170.315(g)(3)(ii), (iv), and (v), making conforming revisions to paragraph (g)(3), and retaining the reference to § 170.315(g)(3) in § 170.550(g)(1). All revisions to the SED certification criterion are effective as of the effective date of this final rule.

d. Quality Management System

In the Proposed Rule (90 FR 60996), we proposed to remove the “quality management system” (QMS) certification criterion in § 170.315(g)(4) and the reference to this certification criterion in § 170.550(g)(2), as of the effective date of this final rule. The QMS certification criterion states for each capability that a technology includes and for which that capability’s certification is sought, the use of a QMS in the development, testing, implementation, and maintenance of that capability must be identified and satisfied in one of the following ways: either the QMS used is established by the Federal Government or a standards development organization (SDO) or the QMS used is mapped to one or more QMS established by the Federal Government or an SDO. Per § 170.550(g), this certification criterion is mandatory for all certified Health IT Modules.

As discussed in the Proposed Rule (90 FR 60996), we proposed to remove this certification criterion because industry and other interested parties now widely implement quality management principles in comparison to when this certification criterion was initially adopted. We determined as a result, that the certification criterion in § 170.315(g)(4), and the related requirement that all Health IT Modules be certified to it, have become duplicative.

Comments. The majority of commenters were not supportive of removing the QMS certification criterion in § 170.315(g)(4). These commenters expressed concerns that removal would weaken baseline safety, quality, and reliability expectations for certified health IT and shift verification responsibilities from developers to providers and purchasers. Many of these

commenters also expressed concerns that removal of the certification criterion could reduce assurances for quality practices, increase the likelihood that immature products enter clinical and operational workflows, and result in inconsistent adoption of quality management practices, including by new market entrants.

Some commenters also noted that removal of this certification criterion could introduce new challenges in evaluating health IT developer safety practices and managing risk, particularly for rural or low-resourced providers with limited technical resources and expertise to independently evaluate the safety, security, and quality of their software systems. Some commenters who opposed removal of the QMS certification criterion recommended that, if the criterion was removed, we provide additional guidance on a replacement approach and how safety, quality, and reliability expectations would be maintained through modernization efforts, including API-based ecosystems and other programmatic mechanisms. Several of these commenters also recommended adopting post-certification oversight and transparency mechanisms to assess the impact of removing this certification requirement and to offer providers information about developers’ capabilities and associated costs.

A small number of commenters supported removing the certification criterion or expressed a neutral view, stating that the requirement can be seen as duplicative since many developers already maintain quality management system practices as part of routine operations.

We received mixed comments regarding the level of burden associated with the QMS certification criterion and whether removal of the criterion would meaningfully reduce burden. As noted above, a few commenters who expressed a neutral view or supported removal of this certification criterion stated that many mature development organizations would continue to maintain quality management practices and follow the ISO industry standard regardless of certification requirements. Other commenters noted that the current QMS certification criterion was burdensome for developers and system administrators and recommended that we should modernize or streamline the requirement rather than remove it.

Response. We thank commenters for their thoughtful feedback. We have not finalized our proposal to remove the quality management system certification criterion in § 170.315(g)(4) or the

corresponding reference in § 170.550(g)(2).

After considering the comments we received, we believe § 170.315(g)(4) continues to serve an important function in the Certification Program by providing a consistent baseline assurance that developers of certified health IT identify and use a quality management system in the development, testing, implementation, and maintenance of certified health IT capabilities. We recognize that many developers of certified health IT already maintain quality management principles and processes as part of routine operations. However, we believe that maintaining a baseline certification requirement at this time is important to ensure continuity of safety and quality practices and to promote consistent expectations across the market, including for new entrants. We recognize that quality management expectations may continue to evolve as part of broader health IT modernization efforts and that the QMS certification criterion continues to support providers and purchasers that rely on certification as a meaningful signal of developer quality management practices. Our decision to retain § 170.315(g)(4) also supports consistency with the Certification Program’s broader approach to transparency and public reporting regarding the quality management processes used by developers for certified health IT.

Comments. Some commenters who opposed removal of the QMS certification criterion expressed concerns about coordination with CMS program timelines and recommended delaying removal of the certification criterion to align with CMS program requirements and reduce potential provider compliance risks.

Response. We acknowledge commenters’ concerns regarding coordination with CMS program timelines and related provider compliance activities. However, while the QMS certification criterion in § 170.315(g)(4) impacts certified health IT used by health care providers for compliance with CMS programs, we are not aware of any direct requirements for adoption or use of certified health IT certified to the QMS certification criterion. For instance, with respect to the Promoting Interoperability program and the MIPS Promoting Interoperability performance category, CMS has not specified the criterion in § 170.315(g)(4) as required to support any of the current measures in the program as part of the definitions of CEHRT in 42 CFR 495.4 or 42 CFR 414.1305. Our decision not to finalize

removal of § 170.315(g)(4) is not based on CMS program dependency, but rather that this certification criterion continues to serve an important role within the Certification Program as a baseline quality management and assurance expectation, as well as to support transparency and maintain consistent adoption of QMS practices over time. Therefore, we have not finalized our proposal to remove the quality management system certification criterion in § 170.315(g)(4) or the corresponding reference in § 170.550(g)(2).

e. Accessibility-Centered Design

In the Proposed Rule (90 FR 60997), we proposed to remove the “accessibility-centered design” (ACD) certification criterion in § 170.315(g)(5) and the corresponding reference to this certification criterion in § 170.550(g)(3) as of the effective date of this final rule. This certification criterion requires that all developers of Health IT Modules identify and use a health IT accessibility-centered design standard or law in the development, testing, implementation, and maintenance of each capability for which certification is sought. We stated that, if finalized, removal of this certification criterion would not exempt health IT developers and providers from their independent obligations under applicable Federal civil rights laws, including Section 504 of the Rehabilitation Act, Section 1557 of the Affordable Care Act, and the Americans with Disabilities Act.

Comments. Most commenters were not supportive of the removal of the ACD certification criterion in § 170.315(g)(5). These commenters expressed concerns that removal of this certification criterion could reduce accessibility and equitable access to certified health IT for individuals with disabilities and weaken a measurable certification baseline for accountability. One of these commenters emphasized that accessibility is not static and requires ongoing monitoring, updates, and testing as platforms evolve. Another commenter remarked that the impact of this certification criterion has not diminished and stated that there is no guarantee that health IT developers will ensure accessibility-centered design practices continue if the ACD certification criterion is removed.

Many commenters who opposed our proposal also expressed concerns that removal of the ACD certification criterion could reduce transparency and incentives to maintain accessibility-centered design practices, leading to uneven adoption, particularly among new market entrants, and widening gaps

in digital participation. A few commenters also emphasized that accessibility-centered design requirements support standardized, interoperable access to health information and expressed concern that removal of this certification criterion could undermine accessibility in API-based and SI-enabled environments. Multiple commenters cautioned that reducing accessibility and usability requirements could increase the risk of inefficient workflows and could lead to an increase in clinician workload and cognitive burden. Many of these commenters expressed concerns that removal of § 170.315(g)(5) would shift costs, usability barriers, and responsibility for ensuring accessibility to providers, patients, and caregivers, including the potential for developers to charge additional fees for accessibility features previously included as part of certified health IT. Some commenters recommended that, if we were to remove § 170.315(g)(5), we should adopt a replacement accountability mechanism and provide transition guidance.

Several commenters who opposed removal of this certification criterion stated that applicable Federal civil rights laws do not serve the same function or provide the same measurable accountability as a Certification Program requirement. A few other commenters argued that removing the ACD certification criterion would not meaningfully reduce burden because some developers would maintain accessibility practices regardless of the certification requirement.

Response. We thank commenters for their thoughtful feedback. We have not finalized our proposal to remove the ACD certification criterion in § 170.315(g)(5) or the corresponding reference in § 170.550(g)(3).

We continue to recognize that accessibility-centered design practices are broadly used across industry. However, we determined that this widespread use of accessibility-centered design practices supports retaining, rather than removing, the ACD certification criterion at this time. We have concluded that § 170.315(g)(5) continues to serve an important function in the Certification Program by maintaining a transparent, measurable baseline regarding the use of accessibility-centered design standards or laws by developers for certified health IT capabilities. We also believe that accessibility is not static and that continued certification transparency and accountability remain important.

The requirements in § 170.315(g)(5) support consistency with the Certification Program’s broader approach to transparency and public reporting regarding the accessibility-centered design standards or laws used in the development of certified health IT. Additionally, retaining § 170.315(g)(5) helps to reduce the risk of uneven adoption or maintenance of accessibility-centered design practices over time, including among new market entrants. Therefore, we have not finalized our proposal to remove the ACD certification criterion in § 170.315(g)(5) or the corresponding reference in § 170.550(g)(3).

Comments. A small number of commenters expressed support for or did not object to the removal of this certification criterion. Most of these commenters stated that this certification requirement is redundant given that accessibility requirements continue to apply under applicable Federal civil rights laws. Additionally, these commenters noted that removal of an attestation-based certification criterion would not meaningfully reduce burden or impact the Certification Program and that the current certification criterion is overly broad or limited in practical utility. A commenter noted that removal of the ACD certification criterion is a simplification measure for the Certification Program. Another commenter stated that accessibility-centered design features should be decided by markets. Several commenters recommended, if § 170.315(g)(5) was removed, that we explicitly clarify in the subsequent final rule that accessibility expectations for developers and healthcare organizations would remain subject to Federal civil rights laws.

Response. We thank commenters for their feedback and continue to believe that § 170.315(g)(5) plays an important role in the Certification Program by providing a transparent and measurable baseline for how health IT developers apply accessibility-centered design standards or laws to certified health IT capabilities. We have not finalized our proposal to remove the ACD certification criterion in § 170.315(g)(5) or the corresponding reference in § 170.550(g)(3).

f. Consolidated CDA Creation Performance

In the Proposed Rule (90 FR 60997), we proposed to remove and reserve the “Consolidated CDA creation performance” certification criterion in § 170.315(g)(6). We also proposed to remove § 170.550(g)(4) which references the certification criterion. We stated that

the certification criterion helps to ensure the proper conformance of Consolidated CDAs (C-CDAs) for transition of care and referral summaries that are sent to and received from external organizations, and that while C-CDA-based standards are still in use, the industry is shifting toward adoption of FHIR-based standards, which are designed to enable greater interoperability and innovation. We stated that we believe that maintaining the current level of support for this and other C-CDA-based criteria, including putting effort and resources toward testing and certification, can detract from industry efforts to move toward FHIR-based solutions, and that removing the certification criterion in § 170.315(g)(6) would contribute to reducing the effort health IT developers and health care providers are focusing on C-CDA support and allow for redirection of efforts toward greater use of FHIR-based standards in health IT. We proposed to remove the Consolidated CDA creation performance certification criterion in § 170.315(g)(6) as of the effective date of this final rule.

Comments. Of the commenters that specifically commented on this proposal, the majority of commenters were not supportive of removing the Consolidated CDA creation performance certification criterion, primarily because they believed that FHIR-based alternatives were not yet mature, finalized, or adopted at scale and that no equivalent FHIR-based replacement had been clearly identified, adopted, or deployed. Many commenters stressed that the current exchange environment remains hybrid, and C-CDA-based document exchange is still foundational, predominant, or widely used, particularly in under-resourced settings. Multiple commenters noted specific use cases that depend on C-CDA-based document exchange, including Healthcare Effectiveness Data and Information Set (HEDIS), risk adjustment, care management, clinical registries and quality measurement, referrals, transitions of care, longitudinal aggregation, encounter notifications, public health, legacy EHR interoperability, patient event notifications, and certain legal documentation. Several commenters stated that C-CDA-based document exchange is better for patients, caregivers, and complete record sharing. Some commenters stressed that C-CDA-based document exchange helps bridge the transition to FHIR by supporting hybrid exchange, mappings, and longitudinal records. A number of commenters were concerned that

removal of C-CDA-based requirements before a FHIR alternative was in place would create a gap and impact interoperability as well as reduce data quality, consistency, predictability, and usability. Several comments warned that removal of C-CDA-based requirements before FHIR-based alternatives are mature and widely adopted could lead to fragmented workflows and increased costs or data exchange burdens for providers.

Response. We thank commenters for these comments regarding FHIR readiness and the removal of the current C-CDA-based certification criterion in § 170.315(g)(6) prior to having a FHIR alternative in place. We appreciate the concerns expressed by commenters that C-CDA-based document exchange is widely used and there is not a mature FHIR-based alternative available at this time. However, we note that the Consolidated CDA creation performance certification criterion in § 170.315(g)(6) has been a conditional, secondary C-CDA implementation requirement applied to health IT for which certification to a primary C-CDA-based certification criterion is sought. For instance, the transitions of care certification criterion in § 170.315(b)(1) includes C-CDA-based requirements, and each product presented for certification to § 170.315(b)(1) would also need to be certified to § 170.315(g)(6) per its additional conformance requirements. It was this second layer of burden we proposed to remove, and we are finalizing the removal of § 170.315(g)(6). Additionally, as discussed earlier in section III.A.2.a, we have extended the timeline for removing the C-CDA-based standards requirements in § 170.315(b)(1) until January 1, 2030. We believe this addresses commenter concerns regarding the immediate removal of C-CDA-based standards requirements from the Certification Program without a viable FHIR alternative. As stated in section III.A.2.a, we explain that significant advances are occurring in the development and adoption of FHIR-based standards, and we anticipate substantial progress by January 1, 2030. Therefore, we do not believe it is necessary to retain this additional C-CDA-based certification requirement in § 170.315(g)(6) in order to ensure an appropriate transition from C-CDA-based standards to FHIR-based standards in the Certification Program. As such, we have finalized the proposal to remove the Consolidated CDA creation performance criterion in § 170.315(g)(6) as of the effective date of this final rule. We have also finalized

the proposal to remove § 170.550(g)(4) as discussed in more detail in section III.E.2.

Comments. Several commenters expressed concerns about patient safety, including concerns that removal of the certification criterion could disrupt continuity of care, care coordination, patient safety, or patient outcomes. Some commenters noted that certification to the criterion in § 170.315(g)(6) is an important safeguard, accountability mechanism, and testing floor.

Response. We thank commenters for expressing these concerns about patient safety, and we appreciate the importance of ensuring that health information is exchanged reliably during transitions of care and in referral summaries. However, as already noted, the certification criterion in § 170.315(g)(6) is not the only certification criterion in the Certification Program that requires use of C-CDA-based standards and that helps ensure reliable data exchange during transitions of care. As discussed in section III.A.2.a, we have extended the deadline for removal of C-CDA-based requirements in the transitions of care certification criterion in § 170.315(b)(1). We believe this extension will provide enough time for certified health IT to move from C-CDA-based standards to FHIR-based standards without sacrificing patient safety. In addition, we reiterate that the removal of the certification criterion does not necessitate removal of the functionality from health IT systems for users who may have these functions implemented, nor does it prohibit continued use of the referenced standards in existing and new health IT implementation.

Comments. A number of commenters expressed concerns about additional burden that the proposal could place on providers, stating that the removal of C-CDA-based exchange requirements could increase manual workflows, reconciliation, quality assurance, testing, normalization, and other administrative burden. Some commented that the proposal could disproportionately burden smaller, rural, safety-net, tribal, post-acute, behavioral health, and similar under-resourced settings. Another commenter stated that the proposal would not reduce developer burden because developers would still need to maintain C-CDA support for the foreseeable future.

Response. We thank commenters for expressing these concerns about burden, and in particular burden on under-resourced providers and settings. We

appreciate the importance of not imposing additional burden on providers by removing requirements related to C-CDA-based exchange. Again, it is important to understand the context associated with this specific certification criterion, which is secondarily applied to health IT certified to a C-CDA referencing criterion. C-CDA IGs have become more rigorous and less ambiguous, and existing test tools and industry experience with C-CDA is far greater now than when this certification criterion was first introduced. Thus, we believe that the continued need for this certification criterion in the Certification Program has concluded. Regarding the comment about the burden reducing impact of this proposal, we believe that even if a developer maintains C-CDA support, removal of this certification criterion would reduce maintenance efforts for developers, including effort and resources that would be put toward testing and certification to this criterion if the criterion remained part of the Certification Program.

Comments. Some commenters expressed disagreement with the general rationale that health IT developers would continue to support C-CDA-based exchange after removal of C-CDA-based exchange requirements in the Certification Program. These commenters were concerned that removal might result in developers charging extra for C-CDA-based exchange functionality once that functionality is no longer part of the certification requirements, and several commenters were concerned that fees to maintain C-CDA-based exchange would harm under-resourced providers and settings. Some commenters had concerns that new entrants to the market might omit core capabilities, implement them inconsistently, use proprietary alternatives, or lack the real-world knowledge needed to support C-CDA-based exchange.

Response. We thank commenters for expressing these concerns about developers, and in particular new entrants to the market, not providing support for C-CDA-based exchange. We appreciate the importance of ensuring that support for this functionality is continued during a transition to FHIR-based exchange, especially for under-resourced providers and settings. As stated above, other certification criteria in the Certification Program also require use of C-CDA-based standards for exchange and can help ensure support during a transition from C-CDA-based exchange to FHIR-based exchange. We have extended the deadline for removal

of C-CDA-based requirements in the transitions of care certification criterion in § 170.315(b)(1) until January 1, 2030. We believe this extension will provide enough time for certified health IT to move from C-CDA-based standards to FHIR-based standards without providers being subject to increased fees or reduced developer support for C-CDA-based exchange during the transition. As noted above, we reiterate that removing this certification criterion neither requires removal of the functionality from existing implementations nor prohibits continued use of the referenced standards in new or existing health IT.

Comments. A number of commenters contended that the timeline was too short and that there was no sufficiently clear phased plan, readiness benchmark, or implementation guidance.

Response. We thank commenters for sharing these concerns regarding timelines and for expressing a desire for a phased plan for transitioning from C-CDA-based exchange to FHIR-based exchange. As discussed in section III.A.2.a, we have finalized an extension of the deadline for removal of C-CDA-based requirements in the transitions of care certification criterion in § 170.315(b)(1). We believe this extension provides a clear and workable timeline for certified health IT to move from C-CDA-based standards to FHIR-based standards. We note that we provide guidance and resources on all Certification Program requirements on our website at [healthit.gov](https://www.healthit.gov) and anticipate that future guidance materials and resources will continue to focus as needed on transitioning from C-CDA-based exchange to FHIR-based exchange.

Comments. Some commenters expressed concerns about alignment with CMS and other Federal or programmatic dependencies, including Promoting Interoperability requirements, measure continuity, reimbursement, and other Federally referenced workflows.

Response. We thank commenters for these comments and appreciate the importance of aligning with CMS and other programs. We are not aware of any CMS requirements that directly require health care providers to adopt or use health IT certified to the certification criterion in § 170.315(g)(6) and thus do not believe that removal of this criterion will lead to regulatory alignment concerns for health care providers participating in CMS programs. With respect to the requirements of the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category,

the certification criterion in § 170.315(g)(6) is not currently identified as required to support any of the measures in these programs as part of their respective definitions of CEHRT in 42 CFR 495.4 and 42 CFR 414.1305.

Comments. Some commenters expressed support for removal of the certification criterion in § 170.315(g)(6), stating that the criterion was duplicative or had limited value and that its removal could simplify certification and allow health IT developers to redirect effort toward FHIR-based solutions.

Response. We thank commenters for these comments in support of our proposal. We agree with commenters that the criterion's impact has waned since it was first adopted, and in particular we note the dependency on the transitions of care certification criterion in § 170.315(b)(1). We agree that removal of the certification criterion in § 170.315(g)(6) will reduce burden on developers of certified health IT and encourage, as well as enable, greater effort to be directed at transitioning to FHIR-based exchange. We have finalized this proposal as proposed.

Comments. Several commenters identified issues that were out of scope for our proposal such as broader incentives or funding to support FHIR adoption and future revisions to other certification criteria to better accommodate technology-neutral or FHIR-based approaches.

Response. We thank commenters for these comments, and as they are out of scope, we decline to finalize the suggested changes in this final rule.

g. Application Access—Patient Selection

In the Proposed Rule, we proposed to remove the “application access—patient selection” certification criterion and reserve § 170.315(g)(7) with an effective date of January 1, 2027. We stated that we reviewed and evaluated the certification criterion in § 170.315(g)(7), seeking to identify ways to reduce burden while still supporting our policy goals. As discussed in the Proposed Rule, the application access—patient selection certification criterion in § 170.315(g)(7) includes the capability to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data (90 FR 60997). We explained that since adoption of the HL7® SMART App Launch Implementation Guide in § 170.215(c), all Health IT Modules certified to the standardized API for patient and

population services certification criterion in § 170.315(g)(10) must support the functional requirement described in § 170.315(g)(7)(i) according to the SMART App Launch Implementation Guide. We further explained that we proposed to remove the corresponding certification criterion in § 170.315(g)(9), and that if we finalize the removal of § 170.315(g)(9), the certification criterion in § 170.315(g)(7) would lose its intended utility. We also stated that we believe that reducing compliance burdens for health IT developers that participate in the Certification Program would foster industry innovation and encourage the development of more creative interoperability solutions (90 FR 60998).

Comments. We received several comments that expressed concern that the removal of § 170.315(g)(7) would undermine the functionality in Health IT Modules without the requirement for health IT developers to certify to the criterion. A commenter also expressed concern that the removal of § 170.315(g)(7) could make implementing SMART App Launch more difficult as health IT developers may not adhere to this functionality without the requirement to certify to § 170.315(g)(7).

Response. We appreciate the comments we received that were concerned about degraded functionality for Health IT Modules if § 170.315(g)(7) is removed. We note that Health IT Modules certified to the standardized API for patient and population services certification criterion in § 170.315(g)(10) must support the functional requirement described in § 170.315(g)(7)(i), and we believe that health IT developers will continue to ensure health IT products meet the same functional requirement without needing to certify to § 170.315(g)(7).

Comments. We received several comments that expressed concern that the removal of § 170.315(g)(7) would create a lack of alignment with the requirements that CMS maintains in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. A number of commenters questioned whether the removal of § 170.315(g)(7) would reduce burden for health IT developers if CMS maintains its requirements in these programs. Some commenters requested that we work with CMS to provide clear guidance and address alignment issues regarding the transition to removal of § 170.315(g)(7). A commenter also suggested that we delay the removal of § 170.315(g)(7) to allow time to address CMS alignment with the removal of the criterion.

Response. We appreciate the comments about alignment with the requirements in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. We noted in the Proposed Rule that the criterion is associated with measures under the Provider to Patient Exchange and Health Information Exchange objectives of the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (90 FR 60998). We do not expect the removal of this criterion to lead to regulatory misalignment with CMS program requirements. Nor do we believe additional time is needed to address CMS alignment. We will coordinate with CMS to update information regarding certification criteria that support measures under these programs to appropriately reflect our final policy to remove the criterion in § 170.315(g)(7).

Comments. We received a number of comments that expressed support for our proposal to remove the criterion. Commenters asserted that the certification criterion in § 170.315(g)(7) should be removed because the requirement is duplicative with the requirements in § 170.315(g)(10). Several commenters stated that the quality of Health IT Modules certified to § 170.315(g)(7) is unlikely to degrade with the removal of § 170.315(g)(7) because the certification criterion is duplicative.

Response. We appreciate the comments we received about the certification criterion in § 170.315(g)(7) being duplicative with the requirements in § 170.315(g)(10). We have finalized the removal of § 170.315(g)(7) with an effective date of January 1, 2027, as proposed. We look forward to ongoing collaboration with public and private sector partners as we implement the provisions of this final rule.

h. Application Access—All Data Request

In the Proposed Rule, we proposed to remove the “application access—all data request” certification criterion in § 170.315(g)(9) with an effective date of January 1, 2027. As discussed in the Proposed Rule, the application access—all data request certification criterion in § 170.315(g)(9) requires the capability to respond to requests for patient data for all of the data classes expressed in the standards in § 170.213 (90 FR 60998). We stated that we believe that removing the certification criterion in § 170.315(g)(9) will reduce administrative burden as well as burden for health IT developers and health care

providers by eliminating the need for developers of certified health IT to certify to the certification criterion in § 170.315(g)(9). We explained that we believe the functionality of the criterion has been widely adopted (as discussed in section III.A) among health IT developers and is not likely to go away as a supported functionality solely because of removal from the Certification Program (90 FR 60998).

Comments. We received a number of comments that expressed concern that the removal of § 170.315(g)(9) would undermine the functionality in Health IT Modules without the requirement for health IT developers to certify to the criterion. Several commenters expressed concern that the removal of § 170.315(g)(9) would threaten the availability of USCDI data for customers of Health IT Modules if developers did not have to certify to the requirement in § 170.315(g)(9). Some commenters stated that they are particularly concerned that new health IT developers might not adhere to the expected functionality even if existing health IT developers are expected to continue to adhere to the requirement.

Response. We appreciate the comments we received that expressed concern about degraded functionality for Health IT Modules if § 170.315(g)(9) is removed. The Certification Program is moving towards a standards-based approach to supporting this and similar functionality, including with the adoption of the “standardized API for patient and population services” (§ 170.315(g)(10)). We expect that health IT developers will continue to meet the needs of their customers and provide the all data request functionality without needing to certify to § 170.315(g)(9). However, we will continue to monitor the support for the all data request functionality in the health IT industry and access to USCDI data.

Comments. We received several comments that expressed concern that the removal of § 170.315(g)(9) would create a lack of alignment with the requirements that CMS maintains in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. A number of commenters questioned if the removal of § 170.315(g)(9) would reduce burden for health IT developers if CMS maintains its requirements in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. Some commenters requested that we work with CMS to provide clear guidance and address alignment issues regarding the transition to remove

§ 170.315(g)(9). A commenter also suggested that we delay the removal of § 170.315(g)(9) to allow time to address CMS alignment with the removal of the criterion.

Response. We appreciate the comments about alignment with the requirements in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category. We noted in the Proposed Rule that the criterion is associated with measures under the Provider to Patient Exchange and Health Information Exchange objectives of the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (90 FR 60998). We do not expect the removal of this criterion to lead to regulatory misalignment with CMS program requirements. Nor do we believe additional time is needed to address CMS alignment. We will coordinate with CMS to update information regarding certification criteria that support measures under these programs to appropriately reflect our final policy to remove the criterion in § 170.315(g)(9).

Comments. We received a number of out of scope comments that requested that we give consideration for strong protections for sensitive data associated with the “application access—all data request” certification criterion or for an alternative certification criterion in the future.

Response. We will continue to monitor access to USCDI data and concerns about protections for sensitive data in the health IT industry. We will consider how to address access to USCDI data further as the health IT industry evolves and whether to adopt new regulations in future rulemaking.

Comments. We received a number of comments that expressed support for our proposal to remove the certification criterion. Commenters asserted that the certification criterion in § 170.315(g)(9) should be removed because certification to § 170.315(g)(9) is a significant burden to health IT developers. Several commenters asserted that they expect health IT developers will continue to adhere to the functionality because the functionality is ubiquitous in the health IT industry and expected for customers of Health IT Modules. Some commenters also suggested that the removal of this criterion could encourage health IT developers to certify to the Certification Program without the need to invest in testing and certifying to § 170.315(g)(9).

Response. We appreciate the comments about the burden. We have finalized the removal of § 170.315(g)(9)

with an effective date of January 1, 2027, as proposed. We look forward to ongoing collaboration with public and private sector partners as we implement the provisions of this final rule.

8. Transport Methods and Other Protocols Certification Criteria

In the Proposed Rule, we proposed to remove the “transport methods and other protocols” certification criteria in § 170.315(h), including § 170.315(h)(1) “direct project” and § 170.315(h)(2) “direct project, edge protocol, and XDR/XDM” as of the effective date of this final rule and to reserve § 170.315(h) in its entirety (90 FR 60998). We stated in the Proposed Rule that we no longer believe there is added benefit to include conformance testing for this functionality in the Certification Program as the functionality is widely relied on and supported in the healthcare industry and would be incorporated in health IT absent the certification criteria. We further explained that we believe that removing these certification criteria could spur further industry innovation by enabling health IT developers to redirect investment in certification and testing for these criteria to new areas (90 FR 60998). As discussed in the Proposed Rule, the certification criterion in § 170.315(h)(1) includes the capability to send and receive according to the Applicability Statement for Secure Health Transport (the primary Direct Specification), and the § 170.315(h)(2) certification criterion is a variation of the § 170.315(h)(1) certification criterion to accommodate implementation differences that combined three standards conformance requirements (the primary Direct standard, the edge protocol, and XDR/XDM handling) (90 FR 60998), which we collectively refer to as “Direct Specification” in this final rule. We also proposed to remove § 170.550(j) “direct project transport method” to conform with our proposal to remove § 170.315(h) (90 FR 61005).

Comments. Several commenters supported our proposal to remove the criteria in § 170.315(h). They stated that the testing process for certifying to § 170.315(h) is particularly burdensome for health IT developers. Some commenters also stated that the testing process for § 170.315(h) is prone to technical difficulties that create additional burden for health IT developers certifying Health IT Modules to § 170.315(h). A number of commenters additionally asserted that they would continue to support the Direct Specification functionality if ONC removes the certification criteria in § 170.315(h).

Response. We appreciate the comments supporting our proposal to remove § 170.315(h). We agree with commenters’ concerns about the burden for health IT developers certifying Health IT Modules to § 170.315(h). We have finalized the removal of § 170.315(h) as of the effective date of this final rule, as proposed. We have also finalized the removal of § 170.550(j) to conform with the removal of § 170.315(h). We look forward to ongoing collaboration with public and private sector partners as we implement the provisions of this final rule.

Comments. Many commenters expressed concern that the removal of § 170.315(h)(1) would lead to degraded functionality or reduce adoption of Direct Specification in Health IT Modules and create interoperability gaps without the criteria in § 170.315(h). A number of commenters emphasized that Direct Specification is widely relied upon in the health IT industry and asserted that an alternative FHIR-based functionality was not ubiquitous enough in the health IT industry to replace Direct Specification if we removed the criterion in § 170.315(h)(1) as it relates to Direct Specification. Some commenters were concerned that the burden of testing would be shifted to customers of Health IT Modules to verify the standard of functionality without ONC support. Several commenters asserted that new health IT developers would be unlikely to support the Direct Project specification if § 170.315(h) is removed. Some commenters also emphasized that they believed § 170.315(h) is necessary to maintain consistent functionality for Direct Specification. A number of commenters encouraged ONC to adopt a phased timeline for the removal of § 170.315(h)(1) to provide a transition period for the industry.

Response. We appreciate the comments we received about the continued availability of Direct Specification functionality. We note that, as we have finalized in section III.A.2.a, we are delaying removal of the technical conformance references in § 170.315(b)(1)(i) that would require a Health IT Module to demonstrate its conformance to send and receive transitions of care/referral summaries through a method that conforms to the Direct Specification certification criteria until January 1, 2030. Therefore, we expect that new health IT developers will continue to certify their Health IT Modules to § 170.315(b)(1)(i), and that health IT developers who develop Health IT Modules certified to § 170.315(b)(1)(i) will continue to support the Direct Specification

functionality in accordance with § 170.315(b)(1)(i). By removing the specific certification criteria adopted at § 170.315(h), we have only removed the criteria for the testing and certification process used by health IT developers that seek to perform the core health information service provider services for the transport standard aspects of the Direct Specification. With the widespread adoption and support of Direct Specification in the health IT industry and the continued adoption of § 170.315(b)(1)(i), we expect that health IT developers performing the capabilities that had been adopted at § 170.315(h) will continue to support Direct Specification without the need for dedicated certification criteria to support industry adoption. Therefore, we expect that customers of Health IT Modules will not be significantly burdened by the removal of § 170.315(h), and we believe that the burden for health IT developers associated with § 170.315(h) is unnecessary to continue in the Certification Program.

Comments. We received several comments that expressed concern that the removal of § 170.315(h) would create a lack of alignment with certain CMS program requirements. Some commenters requested that the removal of § 170.315(h) be coordinated to align with CMS program requirements. A commenter suggested that we delay the removal of § 170.315(h) to align ONC and CMS requirements.

Response. We appreciate the comments we received about alignment with CMS program requirements. The CMS definitions of CEHRT in 42 CFR 495.4 and 42 CFR 414.1305 require use of EHR technology certified to the criteria in the ONC-adopted Base EHR definition. These definitions are applicable to certain CMS programs, including the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category. When we issued the Proposed Rule, in order to meet the Base EHR definition, EHR technology was required to be certified to either § 170.315(h)(1) or (h)(2). However, the § 170.315(h) criteria are not independently required to support any measures in either the Medicare Promoting Interoperability Program or the MIPS Promoting Interoperability performance category. Under the CMS CEHRT definitions, changes to the Base EHR definition, including certification criteria referenced therein, are incorporated into the CEHRT definitions via references in those definitions to the “Base EHR definition (as defined at 45 CFR 170.102).” Further, we coordinated

with CMS on our proposal to remove the criteria in § 170.315(h). Therefore, we do not believe additional coordination with CMS is required in order to ensure the regulatory alignment of program requirements for programs that incorporate the CEHRT definitions, including the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, with our final policy to remove and reserve § 170.315(h).

B. Standards and Implementation Specifications for Health Information Technology

1. Standards and Implementation Specifications

As discussed in the Proposed Rule, we proposed to remove or revise certain certification criteria in the Certification Program in an effort to reduce burden, offer flexibility to both developers and health care providers, as well as to support innovation. Included in certain certification criteria are references to standards. In those instances where we proposed to remove the criterion, we also generally proposed to remove the standard that is referenced from the CFR. Where the certification criterion is not removed as of the effective date of this final rule but allows time for transition until January 1, 2027, we generally proposed to also remove those referenced standards on January 1, 2027. Only in limited circumstances do we retain a standard that is referenced in a certification criterion proposed for removal. We also specifically requested comment on whether we should retain any of the standards and implementation specifications proposed for removal because the standard or implementation specification should be required for purposes of health IT alignment, for instance, when acquiring, implementing or upgrading health IT systems and products consistent with sections 13111 and 13112 of the HITECH Act. In certain instances, we did not propose to remove a standard even though we proposed to remove the certification criterion where the standard is referenced. As noted, under section 3004 of the PHSA, we may adopt standards independently of associated criteria in the Certification Program. Standards adopted in 45 CFR 170 subpart B may be referenced by other HHS programs and policies besides the Certification Program. For example, standards adopted in 45 CFR 170 subpart B, regardless of whether they are associated with health IT certification criteria, are also required for use under sections 13111 and 13112 of the HITECH Act when acquiring,

implementing or upgrading health IT systems and products in certain instances.

We did not propose to remove the standard in § 170.205(o), data segmentation for privacy, because some developers still rely on these standards, which allow health care providers to tag healthcare documents with privacy metadata. We also did not propose to remove the Direct Project transport standard in § 170.202(a)(2) since we realize that the Direct Project standards are widely utilized in various use cases and emphasized that developers may still use these standards even if they are removed from certification criteria.

We proposed a minor revision to § 170.205(d)(2) to add the full name of the HL7 Messaging Standard Version 2.5.1 standard. Lastly, we requested comments on retaining the “Applicability Statement for Secure Health Transport” requirement found in § 170.315(h)(1)(i).

Comments. While many commenters expressed support for the direction and objectives of the Proposed Rule, we also received many comments that expressed concerns with the proposed compliance timelines and transition dates. Some commenters stated that having different removal and transition dates for the majority of certification criteria risks creating discontinuities for providers, potential compromises to operational stability and patient safety, uncertainty, and functional gaps.

Multiple commenters expressed that the proposed timelines were too compressed and did not provide an adequate transition time. Many of these commenters provided suggestions and alternatives that they believed would better reflect vendor development cycles, implementation requirements, workforce constraints, and Federal mandates. Other suggestions included having a single sunset date for all removed criteria at least 24–36 months after publication of a final rule and aligned to the beginning of a calendar year, extending particular criteria removals that impact LTPAC systems, CMS provider mandates, or other providers facing feasibility challenges to 2028, and maintaining C–CDA linked or other legacy related requirements until a defined date in the future. A commenter recommended we “grandfather” existing certifications and allow sufficient time for developers and customers to plan upgrades, contracting, and validation before any criteria are retired, as well as ensure standards remain available through the full transition to avoid compliance gaps.

Response. We thank commenters for their feedback on the proposed

compliance and transition dates. In response to concerns with timelines and compliance gaps, for several certification criteria, we have either revised the effective dates or have not finalized our proposal, such as § 170.315(b)(1), (f)(4), and (f)(7). We refer readers to their respective sections of this final rule for further details. In response to concerns with risks creating discontinuities for providers and functional gaps, we note that the removal of a standard does not require reissuance of a certificate in the Certification Program and the standard can still remain in the product. The removal of a standard from the Certification Program does not necessitate the removal of health IT functions using that standard or preclude the continued use of that standard in Health IT Modules. In future rulemaking when a new standard or a new set of standards are adopted, in particular FHIR-based standards, we intend to consider appropriate timelines for developers to adopt and implement these new standards in any future rulemaking establishing new requirements for the Certification Program.

We have finalized the removal of the following standards as of the effective date of this final rule because they would no longer be referenced in certification criteria in the CFR: transport standards in § 170.202(b), (c) and (e); and functional standards in § 170.204. Because vocabulary standards for representing electronic health information in § 170.207(r) and (s) are referenced in § 170.315(c)(4), which we have finalized our proposal to remove effective January 1, 2027, as discussed in section III.A.3.b., we have also finalized the removal of § 170.207(r) and (s), effective January 1, 2027. We have finalized the removal of the following standards as of the effective date of this final rule since we have finalized the revisions of the associated certification criterion requirements to no longer reference the given standard: the content and exchange standard in § 170.205(r)(1), including the specific document templates in § 170.205(r)(1)(i) through (iii).

We have finalized the removal of content exchange standards and implementation specifications referenced in certification criteria requirements that have expired in § 170.205(k)(1) and (2) from the CFR. We have finalized the removal of API standards that expire on January 1, 2026, in § 170.215(b)(1)(i) and (c)(1), and we also finalized to remove and reserve outdated vocabulary standards in § 170.207(f)(2) and (m)(1).

We have finalized the removal of certain vocabulary standards in order to eliminate outdated standards that are no longer referenced or have expired. Therefore, we have removed vocabulary standards in § 170.207(a)(4), (c)(3), (e)(3) and (4). We also finalized the removal of vocabulary standards in § 170.207(d)(1)(ii) and (d)(1)(iii), from the CFR and reserved these paragraphs.

We have also finalized a minor revision to § 170.205(d)(2) to add the full name of the HL7 Messaging Standard Version 2.5.1 standard.

C. Terms and Definitions

We proposed in the Proposed Rule to remove certain certification criteria from § 170.315 and therefore, we proposed to make conforming edits to the terms and definitions in § 170.102 (90 FR 61001).

1. Base EHR

We proposed to make conforming revisions to the Base EHR definition in § 170.102 based on our proposals to remove certification criteria from the CFR that are currently referenced in § 170.102 (90 FR 61001). In section (3)(i) of the Base EHR definition, we proposed to remove references to § 170.315(a)(14), (g)(7) and (9), and (h)(1) and (2). We proposed to remove these certification criteria from the Base EHR definition because we have proposed to remove those certification criteria from the CFR. We also proposed to move § 170.315(b)(11) to section (3)(i) of the definition and remove and reserve section (3)(ii) and remove section (3)(iii) because the transition date has passed.

Comments. The majority of commenters were supportive of revising the Base EHR definition to remove references to certification criteria proposed for elimination and to streamline related definitions, stating that it would have the benefit of improving clarity and consistency for participants in the Certification Program and reducing confusion associated with outdated or obsolete terminology. Commenters noted that our proposal for revising the Base EHR definition would require additional guidance on transition timing and alignment with CMS CEHRT definitions and CMS payment program requirements that rely on certified functionality.

A commenter urged ONC to ensure that interested parties were aware that privacy and security protections are expected despite no longer being enumerated in the definition. Another commenter recommended including certification criteria to enable baseline functionality aligned with the Centers for Medicare and Medicaid (CMS) Interoperability and Prior Authorization

Rule (CMS–0057–F) and future CMS rulemaking expectations, particularly to ensure accountability for enabling bi-directional data exchange between payer systems and provider electronic health records. Other commenters cautioned that changing the Base EHR definition by removing or weakening capabilities could create operational risk including delays and added costs for procurements and contracts. Another commenter urged ONC to provide explicit clarification regarding CAH applicability and to evaluate whether transition timelines, phased implementation, or rural impact assessments are appropriate.

Response. We thank commenters for their support of us making conforming edits in § 170.102. We have finalized some of the proposed revisions to § 170.102. Specifically, in section (3)(i) of the Base EHR definition, we have finalized the removal of references to § 170.315(g)(7) and (9), and (h)(1) and (2). We have finalized the removal of these certification criteria from the Base EHR definition because we have removed these certification criteria from the CFR. Because we did not finalize our proposal to remove the IDL certification criterion in § 170.315(a)(14), we did not finalize our proposal to remove § 170.315(a)(14) from the Base EHR definition. We have finalized the proposal to move § 170.315(b)(11) to section (3)(i) of the definition and remove and reserve section (3)(ii) and remove section (3)(iii) because the transition date has passed. As we discussed in the Proposed Rule, the Base EHR definition provides a baseline assurance that certified health IT has been developed to possess, at a minimum, a key set of capabilities. We note the Base EHR definition is based on the “Qualified EHR” definition in section 3000(13) of the PHSA (77 FR 54262). As we noted recently, we have generally sought to limit the Base EHR definition to elements required for the Qualified EHR definition in PHSA section 3000 (90 FR 37145).

We are working closely with CMS on timing and alignment. We note that the removal of criteria from the Base EHR definition does not require eligible clinicians, eligible hospitals, and CAHs participating in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category to cease use of these health IT functionalities and standards, nor does it require health IT developers to remove them from certified health IT. CMS Program requirements generally do not prohibit the use of functionalities or standards that are not certified; rather they focus on the use of technologies

that are certified to support specific Promoting Interoperability objectives and measures. Where any of the criteria we have finalized for removal are required to support a CMS program objective or measure, we have taken that use into account in setting transition timelines.

We also want to clarify that the Base EHR definition does not include specific privacy and security-related criteria. However, we have not finalized the removal of the privacy and security related criteria in § 170.315(d)(1) through (13). For commenters' concerns related to contracts, we direct them to the ONC resource, titled "EHR Contracts Untangled."⁴⁷

2. Common Clinical Data Set

We proposed to remove the term Common Clinical Data Set in § 170.102.

Comments. The majority of commenters were supportive of removing the Common Clinical Data Set (CCDS) definition. Some commenters supported relying on the USCDI as the single standardized baseline for certification and data exchange expectations, noting that maintaining both CCDS and USCDI contributes to unnecessary complexity and that a single baseline could improve alignment across programs and support predictable updates.

Response. We have finalized as proposed the removal of the term Common Clinical Data Set in § 170.102. As we discussed in the Proposed Rule, we finalized in the Cures Act Final Rule that the CCDS would no longer be applicable for certified Health IT Modules 24 months after the publication date of the Cures Act Final Rule (85 FR 25671), and then extended that date to December 31, 2022, in the interim final rule titled "Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency" (85 FR 70073). Because § 170.315(b)(6)(ii)(A), which also referenced CCDS, was available for the period before December 31, 2023, we did not propose to remove the definition of CCDS in § 170.102 at that time. However, now that the date of December 31, 2023, has passed and we finalized the removal of § 170.315(b)(6) in the HTI-2 Final Rule (89 FR 101776) and there are no longer any references to CCDS in 45 CFR part 170, we have finalized the removal of the term Common Clinical Data Set in § 170.102.

3. Global Unique Device Identification Database and Production Identifier

Because we proposed to remove the "implantable device list" (IDL) certification criterion in § 170.315(a)(14) (90 FR 60983), we also proposed to remove the associated definitions of Global Unique Device Identification Database and Production Identifier in § 170.102.

Comments. The majority of commenters were supportive of the proposed updates to terms and definitions (including removing the definitions of Global Unique Device Identification Database and Production Identifier). Commenters stated that it would streamline terminology, reduce confusion from obsolete constructs, and improve clarity/regulatory clarity.

Response. We appreciate commenters' support but because we did not finalize our proposal to remove the IDL certification criterion in § 170.315(a)(14), we have not finalized our proposals to remove the terms Global Unique Device Identification Database and Production Identifier from § 170.102. In section A.1.c of this final rule, we have discussed the IDL certification criterion in § 170.315(a)(14). The IDL certification criterion requires Health IT Modules certified to § 170.315(a)(14) to exchange, record, and allow a user to access a list of Unique Device Identifiers (UDIs) associated with a patient's implantable devices. The only references to the Global Unique Device Identification Database and Production Identifier in 45 CFR part 170 are in § 170.315(a)(14). Because we have not finalized the removal of § 170.315(a)(14), we have also not finalized the removal of the definitions Global Unique Device Identification Database and Production Identifier in § 170.102 as the terms are still referenced in 45 CFR part 170.

D. Conditions and Maintenance of Certification Requirements for Health IT Developers

1. Assurances

Because the transition dates in § 170.402(b)(2)(i) and (ii) had passed, we proposed to revise the Maintenance of Certification requirements in § 170.402(b)(2) to remove the transition dates and only include that a health IT developer that must comply with the requirements of § 170.402(a)(4) must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10) (90 FR 61001).

We also proposed additional conforming edits to § 170.402(b).

Because we proposed to remove the requirements in § 170.315(b)(11)(iv) and (v) regarding source attribute support, access, and modification and in § 170.315(b)(11)(vi) regarding intervention risk management for predictive DSIs (90 FR 60987), we also proposed to remove § 170.402(b)(4), which requires health IT developers to review and update as necessary source attribute information and intervention risk management practices (90 FR 61001 and 61002).

Comments. The majority of commenters supported the proposed conforming edits to the Assurances Maintenance of Certification requirements, stating that the proposed revisions would have the benefit of reducing certification/compliance burden and streamlining certification obligations. Some commenters also supported specific technical updates within the Assurances provisions, including removing outdated references related to EHI Export.

Commenters were generally evenly split on supporting or opposing the proposed removal of the Assurances Maintenance requirement in § 170.402(b)(4), with those in support noting that removal of § 170.402(b)(4) would avoid retaining a maintenance requirement for provisions that no longer exist in the related certification criterion. Commenters that opposed the removal of the Assurances Maintenance requirement in § 170.402(b)(4) recommended retaining the associated Assurances Maintenance of Certification requirement in § 170.402(b)(4), consistent with their recommendations for retaining requirements under the DSI criterion for providing source attributes and intervention risk management practices, as described in section III.A.2.e. of this final rule.

Response. We appreciate commenters' support for our proposal to make conforming edits to the Assurances Conditions and Maintenance of Certification requirements and we finalize, as proposed, the revisions. Because the transition dates in § 170.402(b)(2)(i) and (ii) have passed, we have finalized in the Maintenance of Certification requirements in § 170.402(b)(2) the removal of the transition dates and only include that a health IT developer that must comply with the requirements of § 170.402(a)(4) must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10).

With respect to the comments regarding the DSI criterion, we have finalized, as proposed, the removal of § 170.402(b)(4), which requires health IT

⁴⁷ https://healthit.gov/wp-content/uploads/2025/03/EHR_Contracts_Untangled.pdf.

developers to review and update as necessary source attribute information and intervention risk management practices. As discussed in section III.A.2.e. of this final rule, we have finalized removal of source attribute information transparency for evidence-based and predictive decision support interventions in § 170.315(b)(11)(iv), as well as removal of source attribute access and modification requirements and intervention risk management requirements in § 170.315(b)(11)(v) and (vi). Because we have finalized the removal of certain requirements in § 170.315(b)(11), we no longer believe that a maintenance requirement is necessary under § 170.402(b)(4). Therefore, we disagree with commenters who recommended that we retain § 170.402(b)(4), and we have also finalized the removal of § 170.402(b)(4).

2. Application Programming Interfaces

In the Proposed Rule, we explained that because the transition dates in § 170.404(b)(2), (3), and (4) have passed, we proposed to revise the Maintenance of Certification requirements in § 170.404(b) (90 FR 61002). We proposed to revise § 170.404(b)(2) to remove the date, and we proposed to remove paragraphs (b)(3) and (b)(4) entirely as they are outdated and, in the case of (b)(4) because it refers to certification criteria that we also proposed to remove. We proposed to revise § 170.404(c) to update certification criteria referenced in the “Certified API technology” definition. We proposed to remove the reference to “§ 170.315(g)(7) through” and only keep § 170.315(g)(10) in the “Certified API technology” definition because we proposed to remove § 170.315(g)(7) through (9).

Comments. The majority of commenters supported our proposed conforming edits and streamlining of the API Conditions and Maintenance of Certification requirements, stating that they would have the benefit of reducing unnecessary burden while focusing on currently relevant, standards-based APIs and a limited set of meaningful interoperability signals.

Some commenters stated that our proposal for updating these requirements would require additional guidance of how key API transparency, availability, and documentation expectations will be retained and implemented consistently, including clarity on responsibilities and accountability when certified exchange pathways fail.

A commenter requested that we remove the transparency requirement that certified developers publish their

service base URLs publicly in § 170.404(b)(2). The commenter argued that a published URL list could reveal a developer’s customer footprint, the identity of its customers, its approximate market position and growth, and where an emerging competitor is gaining traction. Another commenter opposed eliminating the references to, and functionality associated with, the certification criteria in § 170.315(g)(7) and (g)(9). Another commenter opposed any practical weakening of the API Conditions and Maintenance of Certification requirements, stating that third-party application developers already encounter substantial barriers despite the existing requirements.

Response. We thank commenters for their support of our proposals to make conforming revisions in § 170.404. We also appreciate the concerns raised by commenters regarding continued API transparency, availability, documentation, and accountability. The revisions we have finalized in § 170.404 remove expired transition provisions and obsolete cross-references; they do not reduce or otherwise alter the substantive requirements in § 170.404(a) or the continuing Maintenance of Certification requirements in § 170.404(b)(1) and (2).

We disagree with the commenter who urged us not to retain the public service base URL publication requirement. We did not propose to eliminate the requirement in § 170.404(b)(2). We recognize that publication of service base URLs and related organization details may reveal customer relationships and permit inferences about a developer’s market presence. Nevertheless, public endpoint information enables patients and applications to identify the appropriate deployed API and connect without special effort. The requirement is limited to the service base URLs and related organization details specified in § 170.404(b)(2). The patient access, transparency, and interoperability benefits of endpoint publication outweigh the competitive concerns identified by the commenter, and we, therefore, retain the requirement.

We also disagree that the conforming revision to the definition of “Certified API technology” in § 170.404(c) eliminates or requires discontinuation of the functionality associated with former § 170.315(g)(7) and (g)(9). The revision aligns the definition with the certification criteria that remain in the CFR; it does not independently remove functionality. We agree with the commenter that stated that third-party application developers should not face

practices that impermissibly impede access to or use of certified API technology. We disagree, however, that the conforming revisions finalized in § 170.404 weaken the API Condition and Maintenance of Certification requirements in practice.

Accordingly, we have finalized these proposals as proposed. Because the transition dates in § 170.404(b)(2), (3), and (4) have passed, we have finalized a revision to the Maintenance of Certification requirements in § 170.404(b). We have finalized a revision in § 170.404(b)(2) to remove the date, and we have finalized the removal of paragraphs (b)(3) and (b)(4) entirely as they are outdated and, in the case of (b)(4) because it refers to certification criteria that we have removed. We also finalized a revision in § 170.404(c) to update certification criteria referenced in the “Certified API technology” definition. We have finalized the removal of the reference to “§ 170.315(g)(7) through” and only keep the reference to § 170.315(g)(10) in the “Certified API technology” definition because we have finalized the removal of § 170.315(g)(7) through (9).

3. Real World Testing

Consistent with the “Real World Testing Condition and Maintenance of Certification Requirements Enforcement Discretion Notice”⁴⁸ issued on June 30, 2025, we proposed three deregulatory actions for the Real World Testing (RWT) Condition and Maintenance of Certification requirements under 45 CFR 170.405 (90 FR 61002). First, we proposed to remove the requirement to submit real world testing plans for all real world testing certification criteria (§ 170.405(b)(1)). Second, we proposed to limit full real world testing results reporting (§ 170.405(b)(2)) to only Health IT Modules that are certified to the API certification criteria, which are “standardized API for patient and population services” (§ 170.315(g)(10)); “provider prior authorization API—coverage requirements discovery” (§ 170.315(g)(31)); “provider prior authorization API—documentation templates and rules” (§ 170.315(g)(32)); and “provider prior authorization API—prior authorization support” (§ 170.315(g)(33)). Specifically, we proposed that developers would be expected to report on all health IT certified to any of the certification criteria in § 170.315(g) as of January 1 of the year in which they must complete real world testing. Developers would

⁴⁸ <https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement>.

also need to report on all health IT certified to any of the certification criteria in § 170.315(g) that undergo updates via Inherited Certified Status during the real world testing year. Finally, we proposed to revise the Standards Version Advancement Process (SVAP). For the API-focused certification criteria identified as § 170.315(g) criteria in § 170.405(a), the real world testing SVAP reporting requirements would not change under § 170.405(b). For health IT certified to the remaining RWT certification criteria identified in § 170.405(a), developers would only need to identify in their RWT results their voluntary updates (health IT products, certification criteria, and standards/implementation specifications) to standards and implementation specifications that the National Coordinator has approved through SVAP, which would be consistent with current requirements under 45 CFR 170.405(b)(2)(ii)(C). For clarity, we proposed to capture the SVAP requirement separately in proposed 45 CFR 170.405(b)(2)(iv). We also proposed a revision to § 170.405(b)(8) to cross-reference paragraph (a) of § 170.405 instead of paragraph (b) due to our proposed revisions.

45 CFR 170.405(a)

Comments. A few commenters requested clarification regarding whether full RWT obligations remain applicable to certification criteria outside the API-focused criteria under § 170.405(a), and recommended revisions to the regulation text to remove ambiguity.

Response. The proposed revised text for § 170.405(a) maintained the requirement that health IT developers with one or more Health IT Module(s) certified to any one or more of the Certification Criteria for Health IT in § 170.315(b), (c), (e), (f), (g), and (j) must, on an annual basis, successfully test the real world use of those Health IT Module(s). Therefore, consistent with our proposal, the § 170.405(a) obligation to conduct RWT remains as to the specified criteria in our finalized § 170.405(a), which includes criteria beyond the API-focused criteria. As we noted in the Proposed Rule, certain certification criteria would be fully removed from real world testing requirements by virtue of their proposed removal from the Certification Program (90 FR 61002). We further explained that if, in this final rule, we determined to keep any of the criteria proposed for removal and they are currently identified in the RWT Condition of Certification (45 CFR 170.405(a)), they

would also remain part of the RWT Condition of Certification. As discussed earlier in this preamble, we have retained the following RWT certification criteria that were originally proposed for removal from the Certification Program: “clinical information reconciliation and incorporation” (§ 170.315(b)(2)), “transmission to cancer registries” (§ 170.315(f)(4)), and “transmission to public health agencies—health care surveys” (§ 170.315(f)(7)). Further, we retained the safety-enhanced design (§ 170.315(g)(3)), quality management system (§ 170.315(g)(4)), and accessibility-centered design (§ 170.315(g)(5)) certification criteria. Due to the retention of these three certification criteria, we have slightly modified the proposed regulation text for § 170.405(a) to identify the specific (g) criteria included in RWT comparative to our proposal to include all of the (g) criteria. The (g) certification criteria we retained were not previously included in RWT, and we have never proposed to include them in RWT.

Section 3001(c)(5) of the PHSA (42 U.S.C. 300jj–11) (section 4002 of the Cures Act) requires, as a Condition and Maintenance of Certification under the Certification Program, that health IT developers have successfully tested the real world use of the technology for interoperability in the type of setting in which such technology would be marketed. Section 4003(a)(2) of the Cures Act defines interoperability as health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and does not constitute information blocking as defined in section 3022(a) of the Cures Act, as added by section 4004 of the 21st Century Cures Act (42 U.S.C. 300jj–52(a)). This definition for interoperability was codified in 45 CFR 170.102. As noted in the Proposed Rule, we finalized the implementation of the statute’s real world testing requirements through identification of certification criteria for RWT in 45 CFR 170.405(a). Developers remain obligated to conduct RWT for health IT certified to certification criteria identified in § 170.405(a). Therefore, even with consideration of the removal of certification criteria by this final rule, there is no reason to amend the regulatory text of § 170.405(a) beyond

how we have finalized it compared to our proposal (*i.e.*, specifying the (g) criteria within scope).

Removal of RWT Plan Submission and Reduced RWT Results Reporting

Comments. Several commenters supported our proposal to remove the RWT plan submissions and reduce RWT results reporting, particularly by narrowing reporting obligations to FHIR-based API criteria. These commenters generally argued that the current RWT framework imposes significant administrative and compliance burdens while providing limited practical value. Commenters described the annual testing plans as largely formulative endeavors that consume resources without meaningfully improving interoperability outcomes. These commenters also emphasized that focusing RWT oversight on key API certification criteria—such as § 170.315(g)(10) and the “prior authorization” API criteria—better aligns with ONC’s “FHIR-forward” strategy and concentrates on the interoperability functions most critical to real-world EHI exchange.

A majority of commenters opposed our proposal to remove the RWT plan submissions and reduce RWT results reporting. Commenters asserted that our proposals would weaken developer accountability, interoperability assurance, and patient safety protections (*e.g.*, identifying missing meds, incomplete data). Commenters stressed that publicly available RWT plans and results provide important transparency for healthcare organizations making purchasing and implementation decisions and help smaller providers, rural organizations, and public health agencies assess whether products will function effectively. Commenters argued that reducing RWT reporting to API criteria was premature because there is not yet a fully mature and stable FHIR-based ecosystem. Commenters also argued that the proposed approach could leave important interoperability gaps undetected, such as with public health reporting.

Response. We thank commenters for expressing both their supporting and opposing viewpoints. We have finalized the removal of the RWT plan requirement and the reduced RWT results reporting as proposed. We agree with commenters who stated that the previously codified RWT plans and results reporting requirements created significant burden without meaningful results. An API-focused approach will align with our overall strategy for the Certification Program and support interoperability. Considering the

planned API and FHIR-forward future approach for the Certification Program, we believe that future results reporting will provide the transparency and interoperability assurance advocated for by commenters. For example, as we propose, and should we adopt, more API and FHIR-based certification criteria,⁴⁹ we anticipate that there would continue to be RWT results reporting for those criteria that can provide insights into the interoperability of certified health IT.

While we appreciate commenters' statements that RWT results may be used to inform decisions regarding the purchasing and licensing certified health IT, we believe that, based on our interactions with health care providers and their executives, it is only one of a multitude of factors that they consider. Further, we believe that the current RWT results reporting and anticipated future RWT results reporting related to APIs will provide information that health care providers may find useful in making certified health IT purchasing and licensing decisions.

We also believe that the Certification Program, through conformance testing, ONC-ACB surveillance and corrective action, and ONC direct review, provides the requisite developer accountability and program oversight to provide assurances to consumers and users of certified health IT. These same processes also support patient safety, including through retention of the revised safety-enhanced designed certification criterion (§ 170.315(g)(3)).

SVAP

Comments. We received significant support from commenters for our proposal to streamline the SVAP reporting process, with only a few commenters expressing indirect opposition to the proposal based on their belief that our proposals would reduce overall oversight of the Certification Program. Commenters requested clarification on when SVAP standards must be reported in RWT results reports for non-API criteria, including whether reporting applies to all SVAP standards on the CHPL listing, only those implemented during the applicable calendar year, or only newly added SVAP standards not previously reported. Another commenter questioned the burden of requiring RWT Results Reports solely to restate SVAP information already available on CHPL. A few commenters requested that we

provide clear expectations and transition guidance if RWT requirements change during the 2026–2027 implementation period.

Response. We have finalized with modification our proposed revisions of SVAP. SVAP is a voluntary process that requires affirmative actions by developers to adopt and certify their health IT to a newer version of a standard or implementation specification that is included in certification criteria that are specified in RWT under § 170.405(a). Ultimately, through attestations under 45 CFR 170.406, a developer attests that their certified health IT is conformant to the “SVAP” version of the standard or implementation specification as part of their overall attestation to compliance with 45 CFR 170.405.

Except as follows, we have finalized as proposed our proposed modifications to SVAP. In consideration of the regulatory version updating and attestation processes outlined above and public comment noting that SVAP standards are identified via the CHPL for certified health IT, we have not finalized our proposal to require, as part of RWT results reporting, the identification of any SVAP updates to health IT certified to the non-API RWT certification criteria identified in § 170.405(a) (the non-(g) certification criteria). We believe sufficient assurances and transparency will be provided by the aforementioned attestation and CHPL listings. As a result, there is no need for developers to identify in their RWT results their voluntary updates (health IT products, certification criteria, and standards/implementation specifications). This approach avoids redundancies and further reduces burden. We have, however, finalized our proposal that the RWT SVAP reporting requirements would not change for API-focused certification criteria identified as (g) criteria in § 170.405(a). This is because we proposed that all provisions under § 170.405(b) would still apply to health IT certified to API-focused certification criteria, and we expect such RWT and reporting to occur, including with SVAP versions of standards and implementation specifications, as applicable. For clarity, we have still finalized the proposed revision to § 170.405(b)(8) to cross-reference paragraph (a) of § 170.405 instead of paragraph (b). This will provide the availability of SVAP for all health IT certified to certification criteria identified in § 170.405(a), which supports advancing interoperability. All revisions will be effective upon the effective date of this final rule. As such,

we will implement this approach for the attestation period that begins on January 1, 2027.

Comments. A commenter requested clarification and reconsideration of proposed timelines tied to certification as of January 1 of the testing year, including retention of the existing August 31 threshold date.

Response. We did not propose nor have we finalized any changes to the regulatory timeframes for RWT results reporting.

Comments. Commenters asked what mechanisms we envisioned to ensure ongoing monitoring of SI performance, model evolution, and real-world impact if existing oversight mechanisms are removed.

Response. As the functionality referenced by commenters was removed from the DSI certification criterion through this final rule, it would not be part of RWT. We refer readers to the discussion earlier in the preamble regarding the DSI certification criterion and the final policy determinations (*see* III.A.2.e “Decision Support Interventions”).

Comments. Commenters asked how we would prevent fraud or “low-quality” certification as RWT requirements are reduced. Another commenter recommended that we move to continuous performance monitoring.

Response. ONC maintains a robust oversight framework for the ONC Health IT Certification Program, including the ability for ONC to directly review certified health IT as specified in 45 CFR 170.580. We are confident that sufficient regulatory oversight remains in place notwithstanding the policies we have finalized to remove RWT testing plans and RWT results reporting for limited certification criteria.

Comments. A few commenters provided alternative approaches to RWT than previously codified or proposed in the Proposed Rule. These included suggestions to focus on performance-based metrics such as uptime, latency, error rates, and adoption rates. As one example, a commenter suggested applying a risk-based or scope testing.

Response. We thank commenters for these suggestions, but they are beyond the scope of this rulemaking.

4. Attestations

Because we proposed to remove § 170.315(g)(7) through (9) in the Proposed Rule (90 FR 60998), we also proposed to remove the references to § 170.315(g)(7) through (9) in § 170.406(a)(4). Further, in § 170.406(a)(5), we also proposed to remove the reference to § 170.315(g)(7) through (9). Additionally, we proposed

⁴⁹ See ONC's planned rulemaking that includes API certification criteria: <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202510&RIN=0955-AA10>.

to remove the reference to § 170.315(h) in § 170.406(a)(5) because in the Proposed Rule (90 FR 60998 through 60999), we proposed to remove § 170.315(h)(1) and (2), in effect removing the entirety of § 170.315(h) (90 FR 61003).

Comments. Commenters were supportive of the proposal to make conforming edits to the Attestations Condition of Certification requirements, stating that it would have the benefit of reducing administrative burden, improving clarity, and better aligning requirements with an updated certification framework.

Response. We appreciate commenters' support. We have finalized as proposed conforming edits to the Attestations Condition of Certification requirements. Because we have finalized the removal of § 170.315(g)(7) through (9), we also have removed the references to § 170.315(g)(7) through (9) in § 170.406(a)(4). In § 170.406(a)(5), we also finalized the removal of the reference to § 170.315(g)(7) through (9). Additionally, we have finalized the removal of the reference to § 170.315(h) in § 170.406(a)(5) because, as we discussed in section III.A.8 of this final rule, we have finalized the removal of § 170.315(h)(1) and (2), in effect removing the entirety of § 170.315(h).

5. Insights

As discussed in the Proposed Rule, the Insights Condition (§ 170.407) includes seven measures on which certain health IT developers under the Certification Program must annually report consistent with specified timelines (90 FR 61003).

We explained in the Proposed Rule that consistent with E.O. 14192, "Unleashing Prosperity Through Deregulation,"⁵⁰ we identified certain regulatory requirements for which the exercise of enforcement discretion may prevent or mitigate the accrual of sunk costs by regulated entities, and on April 29, 2025, we published the "Insights Condition and Maintenance of Certification Enforcement Discretion Notice."⁵¹ In the enforcement discretion notice, we stated the enforcement discretion will be in effect beginning on July 1, 2027, and will remain in effect until HHS completes a deregulatory action to remove or revise 45 CFR 170.407 and 170.523(u) (90 FR 61003).

In the Proposed Rule, we proposed to remove the following measures in § 170.407(a)(3):

- § 170.407(a)(3)(i), Individuals' access to electronic health information through certified health IT;
- § 170.407(a)(3)(ii), Consolidated clinical document architecture (C-CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT;
- § 170.407(a)(3)(iii), Applications supported through certified health IT;
- § 170.407(a)(3)(v), Use of FHIR bulk data access through certified health IT;
- § 170.407(a)(3)(vi), Immunization administrations electronically submitted to immunization information systems through certified health IT; and
- § 170.407(a)(3)(vii), Immunization history and forecasts through certified health IT.

We also proposed to make conforming edits to the list structure in § 170.407(a)(3) by redesignating the provision that was in § 170.407(a)(3)(iv) "use of FHIR in apps through certified health IT" instead as paragraph § 170.407(a)(3)(i), as well as to revise § 170.407(a)(1)(ii)(B) and (C) to remove references to the measures that we proposed to remove from § 170.407(a)(3). In addition, we proposed to remove corresponding references to the removed measures in § 170.407(b), as we only expected that health IT developers would report on the "use of FHIR in apps" measure in the newly designated § 170.407(a)(3)(i), specifically, paragraphs (a)(3)(i)(A) and (B) beginning July of 2027 and (a)(3)(i)(C) beginning in July 2028 (90 FR 61003 through 61004).

In the Proposed Rule, we additionally proposed to revise § 170.407(b)(1) to clarify that a developer must provide an annual response to the Insights Condition of Certification if the developer had at least one actively certified Health IT Module as of January 1 of the reporting period (*i.e.*, start of the data collection year) (90 FR 61004). We stated that, if a certified Health IT Module does not meet the eligibility criteria as of January 1 of the reporting period, developers are not required to submit a measure response for that Health IT Module for that calendar year. In this scenario, developers would submit an attestation indicating that they are not required to submit a measure response for that reporting period, and the reason why (they were not eligible as of the January 1st cutoff date). For example, if the certified Health IT Module becomes eligible after January 1st of the reporting period, developers are not required to submit a measure response for that Health IT

Module for that reporting period; they would submit an attestation as described above instead. The developer would submit a measure response the following reporting period for that certified Health IT Module if the certified Health IT Module meets the applicable eligibility criteria as of January 1st of that reporting period.

Lastly, in the Proposed Rule we proposed to revise the name of § 170.407 (Insights Condition and Maintenance of Certification) to simply "Insights" to ensure consistency and uniformity across all the Conditions and Maintenance of Certification in subpart D of 45 CFR part 170 (90 FR 61004).

Comments. We received a number of comments that were supportive of our proposal to remove six of the Insights measures. Commenters stated that the preparations for compliance with the reporting requirements for the Insights measures would have been a significant investment burden for eligible health IT developers. A commenter also asserted that there is no clear connection between the accumulation of data and marketplace improvement. Another commenter expressed support for our approach in the selection of measures for removal in comparison to those we did not propose to remove. Specifically, the commenter noted that data from the "use of FHIR in apps" measure, which we did not propose to remove, could be collected directly by health IT developers for reporting the measure and could therefore create less burden than the other Insights measures.

Response. We thank commenters for their feedback on our proposal to remove six Insights measures. We agree with commenters' perspective that some of the Insights measures would impose significant costs and burden to health IT developers. As we stated in the Proposed Rule, our proposals would ensure that the Insights Condition is aligned with other proposed policies and changes to the Certification Program that prioritize exchange using FHIR-based APIs (90 FR 61004). For the reasons described above regarding the burden to health IT developers and our policies to prioritize exchange using FHIR-based APIs, we have finalized the removal of the following measures as proposed: § 170.407(a)(3)(i) "the individuals' access to electronic health information," § 170.407(a)(3)(ii) "consolidated clinical document architecture (C-CDA) problems, medications, and allergies reconciliation and incorporation," § 170.407(a)(3)(iii) "applications supported," § 170.407(a)(3)(vi) "immunization administrations electronically submitted to immunization information systems,"

⁵⁰ <https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation>.

⁵¹ <https://www.healthit.gov/topic/insights-condition-and-maintenance-certification-enforcement-discretion>.

and § 170.407(a)(3)(vii) “immunization history and forecasts.”

As we discuss hereafter, we have decided not to finalize the removal of the “use of FHIR bulk data access” measure in § 170.407(a)(3)(v) as proposed because we believe that retaining the measure aligns with our FHIR-forward future strategy and our other changes finalized in this rule to prioritize exchange using FHIR-based APIs in the Certification Program. We believe that “use of FHIR bulk data access” measure will provide valuable insights related to the implementation and use of FHIR that will not be captured by the “use of FHIR in apps” measure alone (which, as noted, we did not propose to remove). While we did not finalize the removal of the “use of FHIR bulk data access” measure, we have finalized revisions to § 170.407(b)(1)(i)(B) and (C) to provide more time before reporting of this measure is required. Specifically, we are moving the “use of FHIR bulk data access” measure (previously paragraph (a)(3)(v); paragraph (a)(3)(ii) as finalized in this final rule) from § 170.407(b)(1)(i)(B) to (C). In practice, this means health IT developers will have additional time and will now be required to begin reporting responses for the “use of FHIR bulk data access” measure in July 2029, rather than in July 2028. Developers must collect the required reporting data annually during the preceding year and develop and deploy the technology needed to support data collection in client settings. Considering the timing of the publication of this final rule, there would not be sufficient time for health IT developers to complete these activities in preparation for reporting. Accordingly, moving the reporting start date from July 2028 to July 2029 is appropriate to provide sufficient notice and time for health IT developers to prepare for reporting.

We have finalized conforming edits to the list structure in § 170.407(a)(3) to revise the “use of FHIR in apps through certified health IT” as paragraph (i) instead of (iv) and revise the “use of FHIR bulk data access through certified health IT” as paragraph (ii) instead of (v). We have also finalized conforming edits to § 170.407(a)(1)(ii)(B) and (C) to remove references to the measures that we are removing from § 170.407(a)(3) as well.

Additionally, we have finalized a revision, as proposed, to the name of § 170.407 (Insights Condition and Maintenance of Certification) to simply “Insights” to ensure consistency and uniformity across all the Conditions and

Maintenance of Certification in subpart D of 45 CFR part 170.

Comments. We received several comments regarding our proposal to remove the “use of FHIR bulk data access” measure in § 170.407(a)(3)(v). These commenters stated the “use of FHIR bulk data access” measure is necessary for the measurement of large-scale analytics of app traffic. Commenters also emphasized that the data obtained from the “use of FHIR in apps” measure would be an insufficient substitute for the data that would be obtained from the “use of FHIR bulk data access” measure. Another commenter stated that the “use of FHIR bulk data access” measure would require less effort because it requires tracking minimal data. The commenter also noted that the measure would provide information on the inconsistent implementation of bulk access capabilities. Commenters recommended that ONC retain the “use of FHIR bulk data access” measure to preserve access to information on large-scale data interoperability.

Response. We thank commenters for their feedback regarding our proposal to remove the “use of FHIR bulk data access” measure in § 170.407(a)(3)(v). As discussed above, we have decided to retain the “use of FHIR bulk data access” measure in § 170.407(a)(3)(v) (which we have moved to § 170.407(a)(3)(ii)) and have not finalized the removal of the measure as proposed. We agree with commenters that the “use of FHIR bulk data access” measure should be retained to address gaps in measurement and provide transparency on the use of certified health IT not captured by “the use of FHIR in apps” measure in § 170.407(a)(3)(iv). We adopted the “use of FHIR bulk data access” measure to address gaps in measurement and provide transparency on the use of certified health IT not captured by the “use of FHIR in apps” measure in § 170.407(a)(3)(iv) (88 FR 23840 through 23841). There are a number of reports that the performance of FHIR bulk data access is suboptimal, which could be a result of health IT developers’ implementation of the standard.^{52 53 54}

⁵² Jones, J., et al. Real world performance of the 21st Century Cures Act population-level application programming interface. *Journal of the American Medical Informatics Association*. Vol. 31, Issue 5, 1144–1150. May 2024. Available at <https://doi.org/10.1093/jamia/ocae040>.

⁵³ Re-imagining Public Health Monitoring with Bulk FHIR. SMART. Available at <https://good-neighbor.smarthealthit.org/case-studies/re-imagining-public-health-monitoring-with-bulk-fhir>.

⁵⁴ Bulk FHIR in the Real World: Trially’s CEO Kyle McAllister Shares What Works. Trially. June 29, 2026. Available at <https://www.trially.ai/blog/bulk-fhir-in-the-real-world-trially-ceo-kyle-mcallister-shares-what-works>.

Retaining the “use of FHIR bulk data access” measure in § 170.407(a)(3)(v) will allow us to monitor issues that may be limiting the performance of Bulk FHIR data access by providing insights related to implementation and use of the FHIR standard in large-scale app traffic that Bulk FHIR data access supports. This insight is particularly important as innovators throughout the industry continue to advance bulk data use cases for quality measurement, public health reporting, and clinical research purposes. Retaining the “use of FHIR bulk data access” measure also aligns with our other finalized changes in this rule to prioritize exchange using FHIR-based APIs in the Certification Program by providing insights into the implementation and use of FHIR that will not be captured by the “use of FHIR in apps” measure alone.

Comments. We received a number of comments that broadly opposed our proposal to remove the six identified Insights measures. Commenters stated that the Insights measures would have provided transparency regarding interoperability and FHIR capabilities across health IT products and the health IT industry as a whole. Many commenters emphasized that the data that would have been provided by the Insights measures would be an important tool for accountability in the marketplace for Health IT Modules. Some commenters also suggested that ONC adopt alternative reporting measures that are less burdensome to replace the Insights measures if we finalize the removal of six of the seven Insights measures as proposed.

Response. We appreciate the comments that we received about our proposal to remove the six identified Insights measures. We understand commenters’ concerns about losing access to the data that would have been obtained from the Insights measures that we proposed to remove, but we respectfully disagree with this perspective. We believe that the investment necessary to implement many of the current Insights measures would impose a significant burden on health IT developers that outweighs the benefit we would expect from the data that would have been obtained from the Insights measures for which we have finalized the removal. We clarify that we have not removed the Insights Condition of Certification in its entirety as discussed in detail above. In response to the suggestion that we adopt alternative measures, we will continue to evaluate the Insights measures.

Comments. We received a comment that supported our proposal to revise § 170.407(b)(1) to clarify that a health IT developer must provide an annual response (consisting of either a measure response or an attestation indicating the developer was not eligible for reporting measurement data to the Insights Condition of Certification) if they had at least one actively certified Health IT Module as of January 1 of the reporting period (*i.e.*, start of the data collection year) and continue to have certified health IT under the Certification Program at the time of submission (*i.e.*, July of the following year).

Response. We appreciate the support and have finalized the revision in § 170.407(b)(1) as proposed. A developer must provide an annual response to the Insights Condition of Certification if the developer had at least one actively certified Health IT Module as of January 1 of the reporting period and the Health IT Module remains certified under the Certification Program at the time of submission.

Comments. We received a number of comments specific to our proposals to remove the “immunization administrations electronically submitted to immunization information systems through certified health IT” measure in § 170.407(a)(3)(vi) and the “immunization history and forecasts through certified health IT” measure in § 170.407(a)(3)(vii). Some commenters recommended that ONC retain these measures. Commenters emphasized the significant role that immunization information systems play in public health systems and stated that health care providers and patients would benefit from the two measures providing data on utilization of immunization data exchange and access to immunization data exchange. One commenter asserted that the data that would be obtained from the “immunization administrations electronically submitted to immunization information systems through certified health IT” and the “immunization history and forecasts through certified health IT” measures could be used by public health agencies to improve their awareness of and response to public health threats.

Response. We thank commenters for their feedback. We respectfully disagree with the perspective of the commenters regarding our proposal to remove the “immunization administrations electronically submitted to immunization information systems” measure and “immunization history and forecasts” measure. As we stated in the Proposed Rule, we believe that removing these Insights measures will reduce cost and burden to the public,

and we want to ensure that the Insights Condition is aligned with other policies and changes to the Certification Program that prioritize exchange using FHIR-based APIs (90 FR 61004). We believe that the expected burden to health IT developers outweighs the benefit we would expect from the data that would have been obtained from the measures. Further, we believe the value for public health purposes of the data that would have been obtained from these measures is overstated by commenters, as the data reported for the measures is essentially measuring the total function of the certified Health IT Module, and the data would not include the immunization information that is a part of the immunization information system reporting itself. For these reasons and those stated above, we have finalized the removal of the measures in § 170.407(a)(3)(vi) and § 170.407(a)(3)(vii) as proposed.

Technical Updates in Measure Specification Sheets

In the HTI–1 Final Rule (89 FR 1313), we stated that while the substantive requirements for each measure are defined in rulemaking, we determined that measure specification sheets are a logical and accessible method for the public to also view the technical specification that supports those requirements, and that this is consistent with the approach used by other HHS programs related to measure specifications (*e.g.*, CMS Electronic Clinical Quality Measures (CMS eCQMs)). Additionally, we note that the measure specification sheets provide granular definitions and other information that may be helpful to operationalize the metrics, so they are implemented in a consistent manner across health IT developers.

We also stated that we intend to provide up-to-date measure specification sheets to assist with the regulated community’s understanding of the finalized measures and metric calculations (89 FR 1313). In January 2025, we provided developers of certified health IT updated measure specification sheets for certain measures finalized in the HTI–1 Final Rule, with the flexibility to implement either version 2 or version 4 of the measure specification sheets for the first year of reporting.⁵⁵ We noted that this flexibility is only for the first year of reporting (until July 2027) and that we expect developers to comply with the most up to date version of the measure

specification sheets provided at www.healthit.gov in subsequent years.

E. ONC Health IT Certification Program Administrative Requirements

1. Principles of Proper Conduct for ONC–ACBs

Under the “principles of proper conduct (PoPCs) for ONC–ACBs” in § 170.523, we require ONC–ACBs to provide ONC a “certified product listing” in § 170.523(f), which is a current list of Health IT Modules that have been certified by the ONC–ACB. In the Proposed Rule (90 FR 61004), we proposed to revise § 170.523(f)(1)(viii) to no longer require ONC–ACBs to provide test data versions used and whether any test data was altered for the certification criterion or criteria to which the Health IT Module has been certified. We noted that with this proposed revision, we would still require the test procedure and test tool version used.

We also proposed to make conforming revisions to the PoPCs for ONC–ACBs in § 170.523 by removing cross-references to certain certification criteria that we proposed to remove in the Proposed Rule. Specifically, we proposed to remove and reserve § 170.523(f)(1)(ix) through (xi) which reference the “privacy and security” certification criteria (§ 170.315(d)), the “quality management system” certification criterion (§ 170.315(g)(4)), and the “accessibility-centered design” certification criterion (§ 170.315(g)(5)). We also proposed to remove and reserve § 170.523(f)(1)(xix), which references the “safety-enhanced design” certification criterion (§ 170.315(g)(3)). We also proposed to remove and reserve § 170.523(f)(1)(xxi) because this section includes a reference to § 170.315(b)(11)(vi) related to intervention risk management practices, and we proposed to remove § 170.315(b)(11)(vi) earlier in the Proposed Rule.

Consistent with the proposals related to the RWT Condition and Maintenance of Certification in § 170.405, we proposed to remove the ONC–ACB review and confirmation process for real world testing plans in § 170.523(p)(1) and the reference to submitting real world testing plans in § 170.523(p)(3).

Comments. We received a couple of comments expressing support for our proposals. A commenter stated that they support the proposed administrative updates for ONC–ACBs to remove references to the criteria we proposed to remove and agree with the removal of the requirement to provide test data versions used and whether any test data was altered for the certification criterion

⁵⁵ https://www.healthit.gov/sites/default/files/page/2025-05/insights_measure_spec_sheet_4_fact_sheet_v03.2_508.pdf.

or criteria to which the Health IT Module has been certified. The same commenter recommended that ONC and ONC-ACBs communicate that the absence of certain information on the CHPL does not imply those aspects are unimportant and instead reflect Certification Program changes.

Response. We thank commenters for their support and agree that the absence of certain information on the CHPL does not imply insignificance. As we explained in the Proposed Rule, an analysis of Health IT Modules in the CHPL indicates that the majority of developers do not employ custom data when conducting certification testing but instead utilize the ONC-provided test data, and that due to low user engagement and little variance from the use of ONC-provided test data, documenting the test data provides little value to the public and represents additional administrative burden for both health IT developers and ONC-ACBs. We have finalized our proposal to revise § 170.523(f)(1)(viii) to no longer require ONC-ACBs to provide test data versions used and whether any test data was altered for the certification criterion or criteria to which the Health IT Module has been certified.

We also thank commenters for their support of our proposal to make conforming revisions to the PoPCs for ONC-ACBs by removing cross-references to certain certification criteria that we proposed to remove in the Proposed Rule. We have finalized our proposal to remove and reserve § 170.523(f)(1)(xxi) because this section includes a reference to § 170.315(b)(11)(vi) related to intervention risk management practices, and as discussed in section III.A.2.e, we have finalized our proposal to revise the criterion and remove § 170.315(b)(11)(vi).

We are not finalizing our proposal to remove § 170.523(f)(1)(xix) and instead have finalized a revision to that provision that is consistent with the changes we have finalized for the “safety-enhanced design” certification criteria in § 170.315(g)(3). In section III.A.7.c, we explain that we have not finalized our proposal to remove the safety-enhanced design certification criterion and have determined that the current reporting requirements for the SED certification criterion can be reduced to an attestation-based approach that retains a meaningful certification expectation for safety-enhanced design. Therefore, we have revised § 170.523(f)(1)(xix) to conform with the revisions we have made to the SED certification criterion and eliminated the requirement that each

user-centered design element required to be reported must be at a granular level, which aligns with our attestation-based approach.

Since we have not finalized our proposals to remove the following certification criteria (see sections III.A.4, III.A.7.d and e), we have not finalized the proposed conforming revisions of § 170.523(f)(1)(ix) through (xi) which reference the “privacy and security” certification criteria (§ 170.315(d)), the “quality management system” certification criterion (§ 170.315(g)(4)), and the “accessibility-centered design” certification criterion (§ 170.315(g)(5)).

We have also finalized a revision to the introductory paragraph of § 170.523(f) to remove reference to the Assistant Secretary for Technology Policy (ASTP) as we are no longer dually titled (91 FR 16204). We find good cause to waive the notice and comment requirements of the Administrative Procedure Act (APA) to remove these references to ASTP because we believe adherence to these APA requirements would be unnecessary (5 U.S.C. 553(b)(B)) considering that there is no longer an “Assistant Secretary for Technology Policy.” This revision to remove the references to ASTP could also be considered a matter relating to agency management under 5 U.S.C. 553(a)(2) and therefore not subject to the rulemaking requirements in 5 U.S.C. 553. We discuss this in further detail in section IV.

Lastly, consistent with the changes we have finalized related to the RWT Condition and Maintenance of Certification in § 170.405 (see section III.D.3), we have finalized our proposal to remove the ONC-ACB review and confirmation process for real world testing plans in § 170.523(p)(1) and the reference to submitting real world testing plans in § 170.523(p)(3).

Comments. A commenter provided recommendations that were out of scope for our proposal, including removing the requirements in § 170.523(k) for mandatory disclosures of certain information about certified health IT and removing requirements in § 170.523(m) related to adaptations and updates to certified health IT.

Response. We appreciate the commenter’s feedback, but because we did not propose changes related to these areas in the Proposed Rule, these comments are out of scope and we decline to finalize the recommended changes in this rule.

2. Health IT Module Certification

We proposed to revise the “Health IT Module dependent criteria” in

§ 170.550(g) by removing § 170.550(g)(1) through (4) to conform with our proposals to remove certain certification criteria related to privacy and security, and design and performance (90 FR 61005). We also proposed renumbering the remaining paragraphs in § 170.550(g)(5) and (g)(6) to (g)(1) and (g)(2), respectively. We proposed to remove § 170.550(h) “privacy and security certification framework” and § 170.550(j) “direct project transport method” to also conform with our proposals to remove certification criteria in § 170.315(d) and § 170.315(h).

Lastly, we proposed to revise § 170.550(e) “standards updates” to correct a cross-reference from “§ 171.405(b)(7) or (8)” to “§ 170.405(b)(7) or (8).”

Comments. We received no comments on these proposals.

Response. To conform with the removal of certain certification criteria referenced in § 170.550, we have finalized the removal of § 170.550(g)(4) to remove reference to § 170.315(g)(6) as proposed. We have not finalized our proposal to remove § 170.550(g)(1) through (3), since we did not finalize our proposal to remove § 170.315(g)(3) through (5) (see section III.A.7).

We also proposed to remove § 170.550(h) “privacy and security certification framework” to conform with our proposal to remove certification criteria in § 170.315(d). However, since we did not finalize the removal of certification criteria in § 170.315(d), we have not removed § 170.550(h) as proposed. Instead, we have revised parts of § 170.550(h)(3) to remove references to the certification criteria we have removed from the CFR in this final rule, since they will no longer be referenced in the Certification Program. We have also finalized revisions in § 170.550(h)(3) to remove references to certification criteria that were removed from the Certification Program in past ONC rulemaking but that were inadvertently left unremoved from the regulatory text.⁵⁶ We have finalized the following revisions in § 170.550(h)(3):

- (i) removing reference to § 170.315(a)(12);
- (ii) removing references to § 170.315(a)(10) and (13);
- (iii) removing references to § 170.315(b)(6) through (9);
- (vi) removing reference to § 170.315(e)(2) and (3);
- (viii) removing references to § 170.315(g)(7) through (9); and

⁵⁶ Sections 170.315(a)(10) and (13), (b)(6), and (e)(2) were removed and reserved in the HTI-2 Final Rule (89 FR 101777).

- (ix) removing reference to § 170.315(h).

This finalized policy is an exercise of removing outdated references from the current regulatory text, in addition to certification criteria the removal of which we have finalized in this final rule, which the Certification Program will no longer reference. These changes are consistent with, and naturally arise from, our proposals to remove the underlying certification criteria.

In addition, we have finalized the removal of § 170.550(j) “direct project transport method” as proposed to conform with our finalizing the removal of § 170.315(h)(1). We refer readers to section III.A.8 for further details on the removal of § 170.315(h)(1).

Lastly, we have finalized our proposal to revise § 170.550(e) “standards updates” to correct a cross-reference from “§ 171.405(b)(7) or (8)” to “§ 170.405(b)(8) or (9)” since we intended, as indicated by the preamble of the Proposed Rule (90 FR 61005), to adopt the reference to the real world testing requirements in 45 CFR part 170 instead of 45 CFR part 171. The Proposed Rule preamble and regulation text erroneously indicated the cross-reference to “§ 170.405(b)(7)”, which is a reserved section of the CFR. Instead, in § 170.550(e) we meant to reference “§ 170.405(b)(8) or (9)” as the correct cross-reference to the SVAP. These finalized changes are consistent with our proposed intent to reference the SVAP requirements for real-world testing in § 170.405(b)(8) and (9) (90 FR 61005).

3. Certification to Newer Versions of Certain Standards

We proposed to revise § 170.555, “certification to newer versions of certain standards,” by removing references to the term “Complete EHR” as it is no longer relevant in our Certification Program (90 FR 61005).

Comments. We received no comments on this proposal.

Response. We have finalized as proposed our proposal to remove references to the term “Complete EHR” in § 170.555(b)(2) as the term is no longer relevant in our Certification Program. As stated in the Proposed Rule (90 FR 61005), retaining the references may cause confusion for the public because the ability to maintain “Complete EHR” certification was only permitted with health IT certified to the 2014 Edition certification criteria, and the “Complete EHR” concept was discontinued for the 2015 Edition (80 FR 62719).

4. Effect of Revocation on the Certifications Issued to Health IT Module(s)

We proposed to revise the title of § 170.570 from “Effect of revocation on the certifications issued to Complete EHRs and EHR Module(s)” to “Effect of revocation on the certifications issued to Health IT Module(s)” (90 FR 61005).

Comments. We received no comments on this proposal.

Response. We have finalized as proposed our proposal to revise the title of § 170.570 to “Effect of revocation on the certifications issued to Health IT Module(s).” As discussed in the Proposed Rule, the term “Complete EHRs” is no longer a relevant term in our Certification Program and retaining it may cause confusion for the public. Therefore, we have finalized to revise the title of § 170.570 to further align with our removals of the outdated “Complete EHR” terminology.

IV. Trusted Exchange Framework and Common Agreement—Restoring the Office of the National Coordinator (ONC)

On April 1, 2026, the Department of Health and Human Services (HHS) published a reorganization which reverses the actions that created the management title of Assistant Secretary for Technology Policy (ASTP), removing the title and role from HHS’ leadership structure, and restores the Office of the National Coordinator for Health Information Technology as a singularly titled office.⁵⁷ The roles and responsibilities of the HHS Chief Technology Officer, Office of the HHS Chief Super Intelligence Officer (previously Chief Artificial Intelligence Officer) and Office of the HHS Chief Data Officer will no longer be part of ONC. Therefore, we have removed all references to ASTP within part 172 of 45 CFR, and, as discussed previously, the reference in part 170 of 45 CFR. We find good cause to waive the requirement under 5 U.S.C. 553(b) to publish a notice of proposed rulemaking in the **Federal Register** for these changes. We believe adherence to this requirement would be unnecessary, consistent with 5 U.S.C. § 553(b)(B) because the “Assistant Secretary for Technology Policy” no longer exists, and this finalized policy is only removing these now inaccurate and confusing references from the current regulatory text. The revisions to remove the references to ASTP within parts 170 and 172 of 45 CFR could also be considered a matter relating to agency

management under 5 U.S.C. § 553(a)(2) and therefore not subject to the rulemaking requirements in 5 U.S.C. § 553.

V. Incorporation by Reference

The Office of the Federal Register has established requirements for materials (e.g., standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5). Specifically, 1 CFR 51.5(b) requires agencies to discuss, in the preamble of a final rule, the ways that the materials they incorporate by reference are reasonably available to interested parties and how interested parties can obtain the materials, and to summarize, in the preamble of the final rule, the material they incorporate by reference.

Review of the standards proposed for incorporation by reference is available during the public comment period. To make the material we intend to incorporate by reference reasonably available, we provide a uniform resource locator (URL) for the standard. Standards are directly accessible through the URLs provided. As an alternative, a copy of the standard may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201.

For the HL7 Messaging Standard Version 2.5.1, it was approved for incorporated by reference into § 170.205 as of February 12, 2010 (75 FR 2014, January 13, 2010). Access can be achieved through signing up for a free HL7 account: https://www.hl7.org/implement/standards/product_brief.cfm?product_id=144.

No changes are proposed to the IBR material.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), codified as amended at 44 U.S.C. 3501 *et seq.*, agencies are required to provide notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to the Office of Management and Budget for review and approval. In order to fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency,

⁵⁷ <https://www.govinfo.gov/content/pkg/FR-2026-04-01/pdf/2026-06284.pdf>.

including whether the information will have practical utility;

2. The accuracy of the agency's estimate of the information collection burden, including the validity of the methodology and assumptions used;

3. The quality, utility, and clarity of the information to be collected; and

4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly sought, and considered, public comment on our assumptions as they relate to the PRA requirements summarized in this section.

A. *ONC-ACBs*

As stated in the Proposed Rule (90 FR 61015), we proposed to descope the "Real World Testing" Condition and Maintenance of Certification requirements in § 170.405 with deregulatory actions related to real world testing plans, results, and the use of the standards version advancement process (SVAP). Consistent with these proposals to descope the Real World Testing Condition and Maintenance of Certification requirements, we proposed to make conforming edits in § 170.523(p) to remove the ONC-ACB review and confirmation process for real world testing plans in § 170.523(p)(1), and the submission of real world testing plans in § 170.523(p)(3) which requires ONC-ACBs to collect and report certain information to ONC related to real world testing plans (e.g., verify that the health IT developer submits an annual, publicly available real world testing plan and perform a completeness check). As noted in the Proposed Rule, our proposals would not add any new collection of information burden and would instead reduce reporting burden associated with the proposed deregulatory actions.

In the 2015 Edition proposed rule (80 FR 16894), we estimated fewer than ten annual respondents for all of the regulatory "collection of information" requirements that apply to the ONC-Approved Accreditor (ONC-AA) and ONC-ACBs, including those previously approved by OMB. In the 2015 Edition Final Rule (80 FR 62733), we concluded that the regulatory "collection of information" requirements for the ONC-AA and the ONC-ACBs were not subject to the PRA under 5 CFR 1320.3(c). We continue to estimate less than ten annual respondents for all of the proposed regulatory "collection of

information" requirements for ONC-ACBs under part 170 of title 45, including those previously approved by OMB and proposed in the Proposed Rule. Accordingly, the regulatory "collection of information" requirements under the Certification Program described in this section are not subject to the PRA under 5 CFR 1320.3(c). We welcomed comments on these conclusions and the supporting rationale on which they are based.

Comments. We did not receive comments specific to the collection of information related to real world testing plans, results, and the use of the standards version advancement process (SVAP).

Response. We have finalized the conforming edits in § 170.523(p) to remove the ONC-ACB review and confirmation process for real world testing plans in § 170.523(p)(1) and the submission of real world testing plans in § 170.523(p)(3), which requires ONC-ACBs to collect and report certain information to ONC related to real world testing plans (e.g., verify that the health IT developer submits an annual, publicly available real world testing plan and perform a completeness check). We continue to maintain our past determinations in that we estimate less than ten annual respondents for all the regulatory "collection of information" requirements for ONC-ACBs under part 170 of title 45, including those previously approved by OMB and in this final rule, and that the regulatory "collection of information" requirements under the Certification Program described in this section are not subject to the implementing regulations of the PRA under 5 CFR 1320.3(c). For the cost and burden reduction estimates related to the finalized deregulatory actions, we refer readers to section VII (Regulatory Impact Analysis) of this final rule.

B. *Health IT Developers*

The "Insights" Condition and Maintenance of Certification requirements in § 170.407 include seven measures that health IT developers under the ONC Health IT Certification Program must annually report on consistent with specified regulatory compliance timelines. In the HTI-1 Final Rule (89 FR 1399), we estimated the total crude upper bound burden to be 1,767,692 hours. In the Proposed Rule, we proposed provisions to remove and descope measures associated in § 170.407 to limit reporting requirements only to the "use of FHIR in apps through certified health IT" measure, which would reduce reporting burden for health IT developers

reporting under the Certification Program. We proposed to reduce reporting burden associated with the Insights Condition and Maintenance of Certification requirements and did not propose any new requirements that would add information collection burden.

Comments. We did not receive comments specific to the collection of information from developers related to the Insights Condition and Maintenance of Certification requirements.

Response. Although we proposed provisions to remove and descope measures associated in § 170.407 to limit reporting requirements only to the "use of FHIR in apps through certified health IT" measure, we have decided not to finalize the removal of the "use of FHIR bulk data access" measure due to alignment with our policies to prioritize exchange using FHIR-based APIs in the Certification Program. Even though we have retained the "use of FHIR bulk data access" measure, the finalized removal of the other measures will still reduce reporting burden for health IT developers reporting under the Certification Program. For more detailed discussion of burden reduction estimates of these deregulatory actions associated with the Insights Condition and Maintenance of Certification, we refer readers to section VII (Regulatory Impact Analysis) of this final rule.

VII. Regulatory Impact Analysis

A. *Statement of Need*

ONC continually evaluates the voluntary Certification Program (42 U.S.C. 300jj-11(c)(5)) to improve the interoperability of health IT, while also assessing ways to reduce administrative costs and burden. This final rule is a result of our ongoing evaluation of the Certification Program and aligns with E.O. 14192 on Unleashing Prosperity Through Deregulation. E.O. 14192 was issued January 31, 2025, and sets the Administration's policy to "significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen."⁵⁸ This final rule is an E.O. 14192 deregulatory action and removes and revises several regulations and policies to unleash prosperity. We believe the changes will reduce burden on developers of certified health IT, returning time and effort to them, and in turn, enhancing competition, entrepreneurship, and innovation. These deregulatory actions will reduce

⁵⁸ <https://www.federalregister.gov/d/2025-02345/> p-2.

barriers to entry for novel technologies and digital health solutions, give time back to developers of certified health IT to focus on the needs and requests of their customers, and, overall, advance progress toward nationwide interoperability and universal patient access to their electronic health information.

B. Overall Impact

We have examined the impacts of this rule as required by E.O. 12866, “Regulatory Planning and Review”; E.O. 13132, “Federalism”; E.O. 13563, “Improving Regulation and Regulatory Review”; E.O. 14192, “Unleashing Prosperity Through Deregulation”; section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532); and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354).

1. Regulatory Planning and Review Analysis

This rule is consistent with the policies outlined in EOs 12866, 13563, and 14192. E.O. 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and distributive impacts). E.O. 14192, as noted above, focuses on deregulatory actions and cost savings associated with deregulatory actions. This rulemaking is significant under Section 3(f)(1) of E.O. 12866, and we have prepared an RIA.

a. Costs and Benefits

These finalized deregulatory actions provide substantial relief for developers of certified health IT and significant cost savings realized from the revision and removal of certain program requirements. For the purpose of estimating the cost savings of this rulemaking, we have determined that these policies would continue absent this regulatory action. The cost savings have been estimated using the best available data and modeled on the costs estimated and finalized in prior ONC rulemakings. As articulated in the preamble, these deregulatory actions reduce the effort of developers of certified health IT to meet ongoing program requirements and reduce barriers to entry for new program participants. The actions, importantly, return effort back to developers of certified health IT to innovate their technology and focus on the needs of their clients and end users.

Comments. Multiple commenters argue that the RIA underestimates or

overlooks significant downstream costs that may shift to providers, health information exchanges, networks, and patients when certification criteria are removed. They warn that eliminating requirements—particularly in privacy, security, and interoperability—could increase variability, reduce auditability, and force providers to independently validate or maintain capabilities previously ensured through certification. Safety net and resource—constrained organizations expressed concern that weakened Federal baselines may expose them to security risks, added vendor fees, contractual burdens, and additional operational responsibilities they are not equipped to absorb. Several commenters emphasized that these unintended consequences may widen inequities, especially for small clinics and rural providers, unless ONC fully evaluates downstream impacts and implements post-final monitoring to mitigate burden shifting. Collectively, commenters urged ONC to account for patient harms, civil rights risks, and the ongoing need for reliable, standards-based functionality within its cost-benefit analysis.

Response. This rulemaking and impact analysis examines the continued value of maintaining program requirements weighed against the ongoing cost of that compliance. Our original analysis and public comments helped shape final decisions and economic analyses presented in this finalized impact analysis. The finalized revisions to the Certification Program carefully considered public comments, and, in particular, we have decided not to finalize proposals to remove criteria that enable secure and confidential access and use of patient health information and certain information exchange capabilities. Finalized revisions to the Certification Program largely encompass reductions in the frequency and scope of data reporting and documentation that developers are required to provide to comply with certification, specifically—narrowing requirements for the Real World Testing and Insights Conditions of Certification and removing annual reporting of source attributes for the “decision support interventions” criterion. We proposed to remove 34 criteria and have, instead, finalized the removal of 14 criteria, with some criteria, previously proposed to be removed, revised instead with a narrower scope, retaining essential functionality and standard references to ensure a necessary floor of technical capability are available to all certified health IT users. The decreased regulatory burdens

and estimated cost savings presented in this impact analysis relate to the compliance costs associated with testing and certification and do not fully encompass the total costs of implementing the technology by end-users.

We considered the effects of revisions to the Certification Program on end-users as part of our calculus; however, we have limited data on how revisions to program requirements may affect the availability or functionality of certified health IT to these end-users. It is difficult to estimate the wide variation in how certified health IT is ultimately deployed and implemented by end-users, as well as evaluate how those choices are tied to Certification Program requirements or the requirements and specifications of other programs that adopt certified health IT. For example, we finalized removal of the “direct project” criterion in § 170.315(h)(1) but have retained reference to the Direct Messaging standard in § 170.202(a)(2). Survey data from 2025 show that a majority of hospitals often use the Direct Messaging standard to send and receive information with outside organizations.⁵⁹ However, other electronic exchange methods complement or substitute for this messaging protocol, like those used for network-based exchange via State, national, and qualified health information networks, and use of those methods by hospitals now exceed use of Direct Messaging. This change occurred despite the broad certification of Health IT Modules to the criterion and ubiquitous adoption of certified health IT by hospitals.⁶⁰ We would not anticipate removal of the criterion from the Certification Program to alone affect future use of the standard or the messaging functionality, as health information exchange is multi-faceted and can be driven by compliance with Federal requirements, the needs of the marketplace, and changing norms and behaviors among healthcare organizations.

Other finalized revisions, like the removals of the “family health history” in § 170.315(a)(12) and “care plan” in § 170.315(b)(9) reflect policy shifts from

⁵⁹ Office of the National Coordinator for Health IT. “Methods Used by Hospitals to Engage in Interoperable Exchange” Health IT Quick Stat #70. Available at: <https://healthit.gov/data/quickstats/methods-used-hospitals-engage-interoperable-exchange/>.

⁶⁰ Barker W, Chang W. Hospital Electronic Health Record Adoption, 2008–2024. Office of the National Coordinator for Health Information Technology. Data Brief: 83. June 2026. Available at: <https://healthit.gov/data/data-briefs/non-federal-acute-care-hospital-electronic-health-record-adoption-2008-2024/>.

certified health IT's ability to record certain information alone to making those data and documents available and accessible for information exchange via USCDI. In the ONC Cures Final Rule (85 FR 25642), we finalized the removal of criteria—"smoking status" in § 170.315(a)(11), "problem list" in § 170.315(a)(6), and "medication list" in § 170.315(a)(7)—but those data were also adopted as part of USCDI, ensuring that this patient health information is made available and accessible as required by certification to Health IT Modules that cross-reference the USCDI standard. Finalized removals, like those mentioned above, are consistent with this policy shift, ensuring that data made available and accessible for exchange conform to the standards adopted as part of USCDI. Care Plan and Family Health History are adopted USCDI data elements, as of version 6 finalized in July 2026.⁶¹

In this final rule, and other finalized rulemakings, we acknowledge that regulatory costs incurred by developers of certified health IT may be passed on to end users of certified health IT in the form of increased fees and other costs.⁶² We anticipate that these finalized deregulatory actions will provide immediate relief and reduce ongoing burden on developers of certified health IT, which may result in reduced marginal costs or other cost savings for end users. The monitoring and evaluation of Certification Program requirements and the deployment of certified health IT in real-world settings is a cornerstone of ONC practice. ONC makes nearly all Certification Program data publicly available and searchable via its public website, permitting full transparency about the types of health IT tested and certified by the Certification Program and how that health IT meets specific program requirements. ONC also leads the collection of data via surveys and other instruments about the real-world experiences of health care providers, patients, networks, and digital health companies using or gaining access to certified health IT. This data is also made publicly available and ONC reports extensively on findings in peer-reviewed journals, via its public website, and other venues. ONC's

research informed both deregulatory decision-making and the estimated cost savings presented here. ONC will continue to study and evaluate the development and use of certified health IT, as well as the real-world impact of the Certification Program on providers, networks, and patients.

Comments: Commenters argued that the projected cost savings in the proposed rulemaking are significantly overstated because most certifications involve routine maintenance rather than new development. They note that many features are already implemented, so large claimed savings—such as millions of hours or over a billion dollars—lack evidentiary support. Overall, they believe the RIA misrepresents the true scale of savings by not accounting for the limited effort required to maintain existing capabilities.

Response: We thank commenters for their input. We agree with the commenters' assessment that most certifications are recertifications that require annual maintenance costs rather than new development or integration costs. This impact analysis took a variety of approaches to estimate cost savings, based on the type of deregulatory action. In all cases, our approach to estimating cost savings calculated maintenance costs as a fraction of new development costs finalized in prior ONC rulemakings to estimate cost savings for the revision or removal of a program requirement. For example, in Table R-1: Panel A "Estimates of Annual Labor Hours Saved for the Removal of Certification Criteria," average maintenance costs across all removals was 15% with a maximum maintenance cost of 27% of new development costs. As described in our methodology for removed criteria, we leveraged data and information collected from the developer community, as part of the Department's request for public comment on deregulatory actions. The public feedback and discussions with developers and other interested parties provided additional context on the ongoing costs of meeting certain Certification Program requirements, in addition to the overall value of this compliance on end-users and other entities. This data, and information informed methodologies discussed in detail in the following analyses, provide concrete evidentiary support for estimated cost savings from these deregulatory actions. It is worth noting that the majority of estimated cost savings are derived from the revision of three Certification Program requirements: safety-enhanced design, decision support interventions, and real

world testing. All three requirements involve regular, typically annual effort for developers to test updated or new modules, provide data and documentation on predictive super intelligence models, and plan, measure, and report on metrics for dozens of certification criteria. These cost savings are also in aggregate across all developers of certified health IT. As of April 1, 2026, there are over 450 developers who participated in the Certification Program. Cost savings are calculated for individual criteria and reporting requirements and reflect the current number of developers and products that adopt the criteria or must comply with a reporting requirement. Therefore, more cost savings may flow to certain developers who currently have Health IT Modules certified to more criteria that will be removed from the Certification Program or who are subject to more extensive reporting requirements that this rule revises. On average, we project that a developer of certified health IT may realize \$300,000 to \$400,000 in undiscounted savings annually or roughly the equivalent of two data engineer FTEs. Where applicable, we describe estimation methodologies in more detail for individual policy changes.

Employee Assumptions and Hourly Wage

We have made employee assumptions about the level of expertise needed to complete the requirements that are affected by this final rule. Unless indicated otherwise, for wage calculations for Federal employees and ONC-ACBs, we have correlated the employee's expertise with the corresponding grade and step of an employee classified under the General Schedule (GS) Federal Salary Classification, relying on the associated employee hourly rates for the Washington, DC, locality pay area as published by the OPM for 2025.⁶³ We have assumed that other indirect costs (including benefits) are equal to 100% of pre-tax wages. Therefore, we have doubled the employee's hourly wage to account for other indirect costs. We have concluded that a 100% expenditure on benefits and overhead is an appropriate estimate based on research conducted by HHS.⁶⁴

⁶³ <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/>.

⁶⁴ See U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE), Guidelines for Regulatory Impact Analysis, at 28–30 (2016), available at <https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis>.

⁶¹ Office of the National Coordinator for Health IT, United States Core Data for Interoperability (USCDI). Available at: <https://isp.healthit.gov/united-states-core-data-interoperability-uscdi#uscdi-v6>.

⁶² Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS). 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (85 FR 25642).

Unless otherwise noted, we have consistently used the May 2024 National Occupational Employment and Wage Estimates reported by the U.S. Bureau of Labor Statistics (BLS) to calculate private sector employee wage estimates (e.g., health IT developers, health care providers, HINs, attorneys), as we believe BLS provides the most accurate and comprehensive wage data for private sector positions.⁶⁵ These wage estimates are a national average and we do not consider regional wage variation in our estimates. We also do not consider possible variation in the average wages for software developers in healthcare IT positions versus IT positions, more generally, which the BLS wage estimate is based upon. Just as with the General Schedule Federal Salary Classification calculations, we have assumed that other indirect costs (including benefits) are equal to 100% of pre-tax wages. We requested comments on our methodology for estimating labor costs, including the effects of any regional or IT sector wage variation on our estimates, and received none.

According to the May 2024 BLS occupational employment statistics, the mean hourly wage for a “Software Developer” is \$69.50. As noted previously, we have assumed that other indirect costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including other indirect costs for Software Developers is \$139.00.

Quantifying the Estimated Number of Health IT Developers and Products

Given the wide range of finalized deregulatory actions, we have not adopted a single, overarching approach to calculate the number of health IT developers and products affected by this rulemaking. We believe, however, that each current developer of certified health IT and participant in the Certification Program will be affected by these finalized actions, but that impact will vary, given the breadth and scope of each developer’s participation in the Certification Program. For each set of finalized actions, we describe our methodology for calculating the current number of health IT developers and products affected, and, where applicable, model estimated future counts of developers and products affected. Throughout this impact analysis, we use public Certification Program data to estimate the number of developers and products certified to specific criteria or who must comply with specific requirements. The

estimates reflect program data analyzed, as of April 1, 2026. In total 466 unique developers certified 601 unique products across 693 certificate listings, as of that date.⁶⁶

Number of End Users That Might Be Impacted by ONC’s Regulations

The breadth and scope of the finalized deregulatory actions create immediate and significant cost savings for developers of certified health IT. As we have finalized in prior ONC rulemakings—Cures Act Final Rule (85 FR 25642) and HTI–1 Final Rule (89 FR 1192)—we assume the regulatory costs imposed by those rules on developers may be passed on to end users of their technology in the form of increased fees and other costs. These deregulatory actions, though scoped to provide immediate relief and reduce ongoing burden on developers of certified health IT, may have downstream impacts on technology end users who may benefit from lower marginal costs to license and update their software; focused developer efforts on emerging end user needs; and other forms of innovation that may lead to unquantified benefits and savings for end users. We assume developers of certified health IT will use the cost savings to invest in innovation and emerging technology, rather than directly reduce costs on their end users, but, overall, believe the cost savings will create a net benefit to end users, if not directly as an immediate financial savings.

Costs

We do not expect costs to be associated with the deregulatory finalized actions. We do, however, estimate the costs to review the rule.

All entities affected by this finalized rule spent time to read and understand the rule, resulting in a one-time cost. The current Preamble and regulatory text together contain approximately 80,000 words; we use this as a proxy for the length of the final rule. Consistent with HHS and Federal guidelines, we assume that industry reviewers read at the average adult reading speed of approximately 250 words per minute, so the time to read and understand the regulation would be about 5.3 hours per person (80,000/250 = 320 minutes; 320 minutes/60 minutes (1 hour) = 5.3 hours per person). We received 298 total comment submissions but believe the total number of reviewers to be higher, as official comment submissions may represent

the combined submissions of multiple developers or entities represented by an industry association or other advocacy organization. We also expect that all health IT developers subject to these regulations will review this final rule. We estimate the total number of reviewers by taking the number of health IT developers and adding an estimated number of medical associations that represent health care providers and health information networks, etc. The counts of developers included in Table R–1 were calculated using publicly available Certification Program data available through the CHPL.⁶⁷ We took the number of developers from Table R–1, which is 466 developers and estimated 150 medical associations, patient groups, third-party app developers, and other interested parties.⁶⁸ We then determined that there would likely be 616 entities that would review the rule. As mentioned above, we used the May 2024 National Occupational Employment and Wage Estimates reported by the BLS to calculate private sector employee wage estimates.⁶⁹ We revised our approach from the proposed review cost projection and identified the “Management Analyst” and “Lawyer” positions as comparable to positions that would review the rule. According to the May 2024 BLS occupational employment statistics, the mean hourly wage for a “Management Analyst” is \$55.15 and \$84.84 for a “Lawyer”. As noted previously, we have assumed that other indirect costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including other indirect costs for a Management Analyst is \$110.30 and a Lawyer is \$169.68. We assume that each position represents 50% of the total review hours per comment submission or an average wage of \$139.99. We estimate it took five hours to review the rule by three individuals at an average wage of \$139.99 (5 hours * 3 persons * \$139.99) or \$2,099.85 per reviewer. We multiply this by the total number of reviewers (616) to get the final estimated review cost of this rule—\$1,293,508.

Comments: We received comments that the estimated review cost of the proposed rule of \$284,132 may be understated, with commenters providing their review experience as evidence for how the review cost may be revised. In particular, reviewers noted variation in the total number and

⁶⁷ <https://chpl.healthit.gov>.

⁶⁸ <https://www.ama-assn.org/house-delegates/hod-organization/member-organizations-ama-house-delegates>.

⁶⁹ <https://data.bls.gov/oes/#/industry/000000>.

⁶⁵ <https://data.bls.gov/oes/#/industry/000000>.

⁶⁶ Office of the National Coordinator for Health IT. Certified Health IT Product List (CHPL). Available at: <https://chpl.healthit.gov>.

range of reviewers who may review the rule from any one organization. One organization may employ one to many reviewers across various occupations to review and provide comment.

Response: We thank commenters for their input. An analysis of public comments indicates a total of 298 unique comment submissions, but we believe the total reviewer count to be more—an estimated 616 reviewers. It is always difficult to project the interest and contribution from the public on any one rulemaking. We believe the total word count is a reasonable data point to use to project the estimated amount of time needed to review and respond to the rule. Given public comments and an exact understanding of the total submissions and commenters, we have revised the estimated review costs accordingly, increasing the total time spent per organization and the average wage used per submission, as described above.

Benefits

We expect the finalized deregulatory actions to result in significant benefits for health IT developers, health care providers, ONC-ACBs, ONC-ATLs, and ONC. These expected benefits are detailed below. Generally, these benefits are in the form of cost and time savings and reductions in administrative burden to comply with Certification Program requirements. The actions reduce the scope and breadth of program requirements. The Certification Program revisions provide direct cost savings (quantified, below) to developers of certified health IT and their users (*i.e.*, health care providers) through fewer program requirements and lower regulatory barriers, freeing up time for more innovation and meeting customer needs. In turn, the revised program requirements may reduce the implementation effort on ONC-ACBs, ONC-ATLs, and ONC, which works with ACBs and ATLs to implement program requirements. These savings in time and effort to ONC-ACBs, ONC-ATLs, and ONC can be used toward

remaining program improvement and implementation efforts, enhancing the operation and management of the Certification Program.

1. Removal

1.1 Removal of Certification Criteria

We initially proposed to remove 34 certification criteria. However, based on feedback from multiple commenters we retained or revised about half of these criteria and finalized the removal of 14 certification criteria. One of the 14 removals is the “clinical decision support” (CDS) certification criterion (§ 170.315(a)(9)), which was finalized for removal from the Certification Program in the HTI-1 final rule (89 FR 1281) but is now being removed from the CFR through this final rule. The RIA below accounts for the removals of the other 13 criteria alone. Of these, we have removed 6 criteria as of the effective date of the final rule and the remaining 7 criteria as of January 1, 2027. We developed a common model for estimating cost savings associated with the removal of all certification criteria, described below.

Table R-1, below, provides criterion-level results of our model for the finalized criteria removals. For each certification criterion we identified the original costs to certify to the functionality from prior rules (the lower and upper bounds of “Total Hours” in Table R-1.)^{70 71 72} We then assumed that the annual cost to maintain certification was a small fraction of the initial costs. We are not aware of any published evidence that would directly inform this calculation, and, therefore, developed a novel approach using various

⁷⁰ <https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#p-185>.

⁷¹ <https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and>.

⁷² <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>.

information sources. We defined this fraction (“Final Effort Multiplier” in Table R-1) based on five factors: (1) “Test”: the criterion’s certification conformance method, assuming that criteria with a test procedure had additional maintenance costs while those with a conformance method of attestation had no additional cost beyond what was initially incurred; (2) “Stakeholder feedback”: stakeholder feedback received by ONC through meetings, informal conversations, and letters from impacted parties on effort involved in certifying and updating the specific certification criterion; (3) “Complexity of standard”: whether the criterion referenced a standard and an assessment of the complexity involved in maintaining and updating conformance to that standard over time; (4) “Complexity of test procedure”: an assessment of the complexity of the test procedure or evaluative work to support attestation when it was necessary to undertake the certification process; and (5) “General complexity”: an overall assessment of the complexity of maintaining the certification criterion and underlying functionality.

The “Final Effort Multiplier” is a sum of the five factors listed in the table and described above. We then used this multiplier to determine the annual costs of meeting and maintaining the individual criteria by taking the product of the lower and upper bound “Total Hours”, described above, and this multiplier. We then estimated the lower and upper bounds of “Hours saved” by multiplying the “Annual” hours by the number of products that certify each criterion. The counts of developers and products included in Table R-1 are current as of April 1, 2026. The counts were calculated using publicly available Certification Program data available through the CHPL.⁷³ Although we primarily use the count of products to estimate “Hours saved”, the count of developers is included for reference and comparison.

⁷³ <https://chpl.healthit.gov>.

Table R-1: Panel A – Estimates of Annual Labor Hours Saved for the Removal of Certification Criteria

Criterion	Adjustments					Final Effort Multiplier	Total hours		Annual		Developers certified	Products certified	Hours saved	
	Test	Stakeholder feedback	Complexity of standard	Complexity of test procedure	General complexity		LB	UB	LB	UB			LB	UB
§ 170.315(a)(12)	0%	2%	5%	2%	2%	11%	50	100	5.5	11	258	315	1,733	3,465
§ 170.315(b)(7)	2%	0%	10%	2%	4%	18%	800	1,300	144	234	31	32	4,608	7,488
§ 170.315(b)(8)	2%	0%	10%	2%	4%	18%	800	1,300	144	234	30	31	4,464	7,254
§ 170.315(b)(9)	0%	2%	5%	2%	4%	13%	700	1,000	91	130	36	42	3,822	5,460
§ 170.315(c)(4)	2%	0%	5%	2%	0%	9%	1,000	1,500	90	135	55	59	5,310	7,965
§ 170.315(e)(3)	0%	2%	0%	2%	2%	6%	500	800	30	48	218	272	8,160	13,056
§ 170.315(g)(1)	2%	6%	0%	4%	4%	16%	800	1,200	128	192	22	25	3,200	4,800
§ 170.315(g)(2)	2%	6%	0%	4%	4%	16%	1,000	1,600	160	256	219	271	43,360	69,376
§ 170.315(g)(6)	2%	4%	10%	2%	4%	22%	400	900	88	198	280	349	30,712	69,102
§ 170.315(g)(7)	0%	0%	0%	4%	4%	8%	300	400	24	32	238	285	6,840	9,120
§ 170.315(g)(9)	2%	4%	10%	4%	4%	24%	300	400	72	96	234	280	20,160	26,880
§ 170.315(h)(1)	2%	4%	10%	2%	4%	22%	800	1,100	176	242	178	207	36,432	50,094
§ 170.315(h)(2)	2%	4%	15%	2%	4%	27%	800	1,100	216	297	16	16	3,456	4,752
All Criteria	--	--	--	--	--	--	--	--	--	--	466	601	172,257	278,812

Table R-1: Panel B – Annual Undiscounted Cost Savings Estimates for the Removal of Certification Criteria

Criterion	Name	Lower Bound	Upper Bound
§ 170.315(a)(12)	Family health history	\$ 240,887	\$ 481,635
§ 170.315(b)(7)	Security tags - summary of care - send	\$ 640,512	\$ 1,040,832
§ 170.315(b)(8)	Security tags - summary of care - receive	\$ 620,496	\$ 1,008,306
§ 170.315(b)(9)	Care plan	\$ 531,258	\$ 758,940
§ 170.315(c)(4)	Clinical quality measures (CQMs) – filter	\$ 738,090	\$ 1,107,135
§ 170.315(e)(3)	Patient health information capture	\$ 1,134,240	\$ 1,814,784
§ 170.315(g)(1)	Automated numerator recording	\$ 444,800	\$ 667,200
§ 170.315(g)(2)	Automated measure calculation	\$ 6,027,040	\$ 9,643,264
§ 170.315(g)(6)	Consolidated CDA creation performance	\$ 4,268,968	\$ 9,605,178
§ 170.315(g)(7)	Application access – patient selection	\$ 950,760	\$ 1,267,680
§ 170.315(g)(9)	Application access – all data request	\$ 2,802,240	\$ 3,736,320
§ 170.315(h)(1)	Direct Project	\$ 5,064,048	\$ 6,963,066
§ 170.315(h)(2)	Direct Project, Edge Protocol, and XDR/XDM	\$ 480,384	\$ 660,528
Total Cost Savings:		\$ 23,943,723	\$ 38,754,868

Note: The lower and upper bound cost savings estimates use the hourly wage (\$139.00) we describe above in “Employee Assumptions and Hourly Wage”.

For the 13 certification criteria finalized for removal in Table R–1, we estimate the total annual hours saved to range from 172,257 to 278,812, among 466 developers of certified health IT and 601 certified products (Table R–1). Using the hourly labor rate (\$139), described above, we estimate the total

undiscounted annual cost savings to range from \$23,943,723 to \$38,754,868. We received no direct comments on the proposed methodology and the accuracy and validity of the model’s estimates. We did receive comments responded to elsewhere on the overall cost saving projections and responded to those by

pointing to the specific analyses, which provide the specific methodologies, assumptions, and evidence used to estimate these cost savings.

2. Revisions

2.1 Revision of Certification Criteria

We have finalized the revision of 5 certification criteria, 2 of which were proposed for removal. For each revised certification criterion, we have estimated the annual savings generated by the finalized revisions.

2.1.1 § 170.315(b)(1) Transitions of Care

We have finalized revisions to the certification criterion in § 170.315(b)(1) to reduce burden on developers of health IT by removing the “send and receive via edge protocol” C–CDA requirement and “create” C–CDA requirement in the criterion and by simplifying the remaining criterion requirements to focus solely on validating receipt of C–CDA documents. We originally proposed to revise the certification criterion with an effective date of January 1, 2027. We have finalized the criterion revisions to be effective as of January 1, 2030. We believe that these revisions remove a substantial proportion of the ongoing effort required to maintain and update the functional requirement of the certification criterion, but we acknowledge that it does not remove requirements to support the C–CDA standard or to update functionality to receive C–CDA documents. We assume that this reduces the overall ongoing cost for this certification criterion by 60%. Following the methodology described for removed criterion, we considered annual maintenance of § 170.315(b)(1) to represent high complexity equivalent to 15% of the initial development costs annually. We note from an analysis of current Certification Program data that 254 developers have certified 294 products to § 170.315(b)(1) and that the initial developer hours estimated to implement the criterion had a lower bound of 3,000 hours and an upper bound of 4,000 hours in the 2015 Edition Final Rule (80 FR 62602).⁷⁴ We therefore estimate that the revision of this criterion will reduce effort to maintain the criterion annually by 9% annually or between 270 and 360 hours per product and 79,380 to 105,840 hours across all products. We estimate the total undiscounted annual cost savings to range from \$11,033,820 to \$14,711,760, beginning in 2030.

2.1.2 § 170.315(b)(2) Clinical Information Reconciliation and Incorporation

We proposed to remove the certification criterion in § 170.315(b)(2). We have not finalized as proposed, and, instead, have revised the certification criterion in § 170.315(b)(2) to reduce burden on developers of health IT by removing the standards-based requirements while maintaining the capability to reconcile and incorporate patient health information electronically. Following the methodology described for removed criterion, we consider § 170.315(b)(2) to represent high complexity equivalent to 28% of the initial development costs annually, of which 8% of this maintenance effort is attributable to the complexity of the test procedure and 10% is attributable to the complexity of the referenced standard. We note from an analysis of current Certification Program data that 217 developers have certified 255 products to § 170.315(b)(2) and that the initial developer hours estimated to implement the criterion had a lower bound of 200 hours and an upper bound of 600 hours. We therefore estimate that the revision of this certification criterion will reduce effort to maintain the criterion annually by 18% annually or between 44 and 132 hours per product and 11,220 to 33,660 hours across all products. We estimate the total undiscounted annual cost savings to range from \$1,559,580 to \$4,678,740.

2.1.3 § 170.315(b)(11) Decision Support Interventions

We have finalized as proposed to remove all requirements related to source attribute support for predictive DSIs and evidence-based DSIs, requirements for source attribute access and modification, and requirements to manage risks related to the development of predictive DSIs.

In the HTI–1 Final Rule, we indicated that the costs to implement § 170.315(b)(11) ranged from 2,200 hours to 4,600 hours, that updating source attribute information annually would cost an additional 0 to 800 hours annually, depending on the number of DSIs the developer supplied, and that engaging in risk management and updating information would result in an additional 0 to 285 hours annually. Without this revision, we estimate that annual maintenance costs for this criterion would represent 12% of initial development costs. We believe these changes reduce these costs by 80% and would eliminate annual costs to update

information for source attributes and risk management.

In total, we estimate that the revision will reduce maintenance costs by 211 to 1,527 hours per product. We note that 251 products developed by 206 developers were certified to § 170.315(b)(11) resulting in an annual reduction of 52,961 to 383,277 labor hours. We estimate the total undiscounted annual cost savings to range from \$7,361,579 to \$53,275,503.

2.1.4 § 170.315(c)(3) Clinical Quality Measures (CQMs)—Report

We have finalized as proposed revisions to § 170.315(c)(3) to remove expired standards references. These revisions are considered de minimis and do not create net new cost savings.

2.1.5 § 170.315(e)(1) View, Download and Transmit to a 3rd Party

We have finalized as proposed to revise § 170.315(e)(1) to remove the standards referenced in § 170.315(e)(1)(i), Web Content Accessibility Guidelines (WCAG) 2.0, and § 170.315(e)(1)(ii), Network Time Protocol (NTP) standard. We believe that the requirement to demonstrate conformance to the WCAG standard creates substantial burden for developers. We received feedback from developers that licensing a tool for WCAG assessments costs thousands of dollars annually. We acknowledge that the current referenced standards are old and do not easily work with newer versions of both the standard itself as well as testing tools to determine compliance. Thus, we expect these changes will reduce unnecessary burden associated with maintaining current conformance requirements as part of certification. In total, we estimate that the annual maintenance burden associated with the WCAG standard represented 2% of the initial development costs of the VDT criterion. We note that 212 developers have certified 248 products to § 170.315(e)(1) and that the initial developer hours estimated to implement the criterion had a lower bound of 1,300 hours and an upper bound of 2,000 hours in the 2015 Edition Final Rule which included the updated WCAG requirement. We therefore estimate that the revision of this criterion will reduce effort to maintain the criterion annually by 2% annually or between 26 and 40 hours per product and 6,448 to 9,920 hours across all products. We estimate the total undiscounted annual cost savings to range from \$896,272 to \$1,378,880.

⁷⁴ <https://www.federalregister.gov/d/2015-25597/p-1773>.

2.1.6 § 170.315(f)(6) Transmission to Public Health Agencies—Antimicrobial Use and Resistance Reporting

We have finalized as proposed to remove the standards-based requirements in § 170.315(f)(6) that were adopted in the 2015 Edition Final Rule and revise this criterion to be a functional criterion. We received stakeholder feedback that the CDA-based standards cited in this criterion are not required for users to submit antimicrobial use and resistance (AUR) data to the CDC's National Healthcare Safety Network (NHSN), creating a disconnect between the criterion and what is used in practice. We expect the removal of standards-based requirements to better align with the NHSN's goals for reporting and reduce the burden on developers to meet this requirement. Following the methodology described for removed criteria, we considered annual maintenance of § 170.315(f)(6) to represent medium complexity equivalent to 20% of the initial development costs annually. We estimate that removal of standards-based requirements will reduce annual maintenance costs to 10% of initial development costs, resulting in a 50% reduction in effort.

Currently, 29 developers and 46 products are certified to § 170.315(f)(6). The initial developer hours estimated to implement the criterion had a lower bound of 1,000 hours and an upper bound of 1,400 hours in the 2015 Edition. We therefore estimate that the revision of this criterion will reduce effort to maintain the criterion annually by 10% or between 100 to 140 hours per product and 4,600 to 6,440 hours across all products. We estimate the total undiscounted annual cost savings to range from \$639,400 to \$895,160.

2.1.7 170.315(g)(3) Safety-Enhanced Design

In the Proposed Rule, we proposed to remove the § 170.315(g)(3) "safety-enhanced design (SED)" certification criterion, but we have decided to revise the criterion rather than remove it from the Certification Program. The revised criterion, however, removes much of the original effort involved in meeting the criterion's objectives. The impact analysis, below, provides an updated estimate of the total time savings associated with this removal and effort retained to meet revised criterion requirements.

In the 2015 Edition Final Rule, we estimated that developers would spend 300 to 400 hours implementing the SED criterion at a cost of \$63 per hour and that 266 developers would certify to SED. This resulted in a final cost estimate ranging from \$5,027,400 to \$6,703,200 in 2014 dollars. Since the finalization of that policy, we have received substantial input from developers of certified health IT that the cost estimates specified in that rule were an under-estimate of the initial and recurring costs associated with the SED certification criterion. In contrast to those estimates, we understand from conversations and fact-finding from developers of certified health IT that individual developers may incur recurring costs greater than \$200,000 to recruit participants and conduct testing specified by the SED certification criterion. In response to input from the impacted community, we have revised our estimates of the costs of SED and potential cost savings that can be realized from the revision of the SED certification criterion in this final rule.

The SED certification criterion is required for all developers seeking certification to § 170.315(a)(1) through

(5), (9) (for the period before January 1, 2025), (a)(14), (b)(2), (b)(3) or (b)(11). Developers must recruit at least ten participants, conduct testing, and submit metrics for each of the criterion for which they seek certification that is referenced within § 170.315(g)(3). Thus, we believe cost savings from the removal of SED are incremental per the number of dependent criteria certified because there are additional costs per product associated with SED testing and data reporting. Based on stakeholder input and because developers can certify multiple products each with up to ten criteria that require SED, we believe an estimated annual cost of between \$8,000 and \$12,000 per product per certification criterion that requires SED testing is appropriate. This estimate represents the effort to design tests, recruit participants, conduct testing, document that testing, and report results to the ONC-ACB in the required format. These costs are borne by both developers presenting a product for the first time and by those developers who must re-certify currently certified products, which may occur on an annual basis.

To estimate the total costs of SED, we estimated the number of products that will be certified to SED and the number of SED criteria each product will certify. We report those costs in Table R-2. The count of products that are certified to SED and number of SED criteria each product certifies in the table are current as of April 1, 2026. The counts were calculated using publicly available Certification Program data available through the CHPL.⁷⁵

⁷⁵ <https://chpl.healthit.gov>.

Table R-2: Annual Cost Savings Estimates for Revision of § 170.315(g)(3)

Number of SED Criteria Certified	Number of Products	Lower Bound Cost Per Product (\$)	Upper Bound Cost Per Product (\$)	Total Lower Bound Cost (\$)	Total Upper Bound Cost (\$)
1	16	8,000	12,000	128,000	192,000
2	3	8,000	12,000	48,000	72,000
3	8	8,000	12,000	192,000	288,000
4	22	8,000	12,000	704,000	1,056,000
5	25	8,000	12,000	1,000,000	1,500,000
6	32	8,000	12,000	1,536,000	2,304,000
7	37	8,000	12,000	2,072,000	3,108,000
8	62	8,000	12,000	3,968,000	5,952,000
9	161	8,000	12,000	11,592,000	17,388,000
Total	366	152,806	229,209	21,240,000	31,860,000
(Minus) Attestation Effort	366	-14,640	-29,280	-2,034,960	-4,069,920
Total Savings	366	138,166	199,929	19,205,040	27,790,080

Note: The lower and upper bound cost estimates use the hourly wage (\$139.00) we describe above in “Employee Assumptions and Hourly Wage”.

In total, 366 products are certified to SED and at least one SED certification criterion. Based on Table R–2, we estimate the total undiscounted annual cost savings from removing these SED certification criterion requirements to be between \$21,240,000 and \$31,860,000. We estimate the total estimated hours saved to range from 153,000 to 229,000 annually across all 366 products or approximately 400 to 600 hours saved per product. In this rule, we decided to revise and retain this criterion, rather than fully remove it from the Certification Program. Specifically, we have finalized the revision of § 170.315(g)(3) to an attestation-based certification requirement. The total cost savings estimated above reflect the effort on developers to recruit participants, plan and conduct testing, and submit

results. Those requirements are now removed as of the effective date of this rule. However, there remains some effort on developers to complete and submit their required attestation. We estimate this new attestation-based requirement would range from 40 to 80 hours of effort per product, modeling the total cost to implement similar to other attestation-based criteria. Multiplying the hourly effort by the total number of products (366) and wage rate of \$139, we estimate that this level of effort will equal between \$2,034,960 to \$4,069,920 annually. Subtracting this from the total cost savings estimated for the removal of the criterion’s other requirements, we estimate net annual undiscounted cost savings for the revision of the SED criterion to range from \$19,205,040 to \$27,790,080. We

estimate the total estimated net hours saved to range from 138,000 to 200,000 annually across all 366 products or approximately 360 to 520 hours saved per product.

In Tables R–2 and R–3, we estimate the combined total annual hours saved from the finalized criteria revisions to range from 292,775 to 739,321 among 323 developers of certified health IT and 399 certified products. Using the labor rate of \$139, described above, we estimate the total undiscounted annual cost savings to range from \$40,695,691 to \$102,765,568. We received no direct comments on the proposed methodology and the accuracy and validity of the model’s estimates. We did receive comments responded to elsewhere on the overall cost saving projections and responded to those by

pointing to the specific analyses that provide the methodologies and assumptions used to estimate these cost savings.

Table R-3 – Panel A: Estimates of Labor Hours Saved for the Revisions of Certification Criteria

Criterion Citation	Total Hours		Annual Hours		Percent Effort Saved	Developers Certified	Products Certified	Hours Saved	
	LB	UB	LB	UB				LB	UB
§ 170.315(b)(1)	3,000	4,000	450	600	60%	254	294	79,380	105,840
§ 170.315(b)(2)	200	600	56	168	79%	217	255	11,220	33,915
§ 170.315(b)(11)									
Task 1	2,200	4,600	264	552	80%	206	251	52,961	110,942
Task 2	0	1,085	0	0	100%	206	251	0	272,335
§ 170.315(e)(1)	1,300	2,000	130	200	20%	212	248	6,448	9,920
§ 170.315(f)(6)	1,000	1,400	200	280	50%	29	46	4,600	6,440
All criteria						323	399	154,609	539,392

Table R-3 – Panel B: Annual Cost Savings Estimates for Revisions of Certification Criteria

Criterion Citation	Annual Cost Savings	
	LB	UB
§ 170.315(b)(1)	\$ 11,033,820	\$ 14,711,760
§ 170.315(b)(2)	\$ 1,559,580	\$ 4,714,185
§ 170.315(b)(11)	\$ 7,361,579	\$ 53,275,503
§ 170.315(e)(1)	\$ 896,272	\$ 1,378,880
§ 170.315(f)(6)	\$ 639,400	\$ 895,160
Total Annual Cost Savings:	\$ 21,490,651	\$ 74,975,488

Note: The lower and upper bound cost estimates use the hourly wage (\$139.00) we describe above in “Employee Assumptions and Hourly Wage”.

2.2 Revisions to Standards and Implementation Specifications for Health Information Technology

We have finalized no revisions to standards and implementation specifications that create new costs or cost savings.

2.3 Revisions to the ONC Health IT Certification Program Administration

Unless noted differently, finalized revisions to Certification Program administration conform to revisions finalized elsewhere related to Certification Program requirements. We do not assess net new cost savings or costs to program administration for these conforming revisions. We did not receive comments on whether these conforming revisions create net new cost savings or costs.

2.3.1 Principles of Proper Conduct for ONC-ACBs

Under the principles of proper conduct for ONC-ACBs, we have finalized as proposed to revise the

“certified product listing” principle in § 170.523(f)(1)(viii) to remove requirements for ONC-ACBs to include the test data version used and whether any test data was altered for the certification criterion or criteria to which the Health IT Module has been certified. This finalized revision is meant to reduce the overall effort for ONC-ACBs for this principle, as our analysis shows that these data elements for the “certified product listing” are of low value. We determined that the cost savings to ONC-ACBs are de minimis and did not receive comments on this analysis. In addition, we have finalized as proposed conforming revisions to the principles of proper conduct for ONC-ACBs. These conforming revisions do not create net new cost savings to developers of certified health IT, ONC, or ONC-ACBs. These conform to revisions made elsewhere to Certification Program requirements, and cost savings, if applicable, are assessed elsewhere in this impact analysis.

2.3.2 Principles of Proper Conduct for ONC-ATLs

We have finalized conforming revisions to the principles of proper conduct for ONC-ATLs. These conforming revisions do not create net new cost savings to developers of certified health IT, ONC, or ONC-ATLs. These conform to revisions made elsewhere to Certification Program requirements, and cost savings, if applicable, are assessed elsewhere in this impact analysis.

2.3.3 Health IT Module Certification

We have finalized conforming revisions to Health IT Module certification. These conforming revisions do not create net new cost savings to developers of certified health IT, ONC, or ONC-ACBs. These conform to revisions made elsewhere to Certification Program requirements, and cost savings, if applicable, are assessed elsewhere in this impact analysis.

2.3.4 Certification to Newer Versions of Certain Standards

We have finalized conforming revisions to certification to newer versions of certain standards. These conforming revisions do not create net new cost savings to developers of certified health IT, ONC, or ONC-ACBs. These conform to revisions made elsewhere to Certification Program requirements, and cost savings, if applicable, are assessed elsewhere in this impact analysis.

2.3.5 Effect of Revocation on the Certifications Issued to Health IT Module(s)

We have finalized conforming revisions that do not create net new cost savings.

2.4 Revisions to Conditions and Maintenance of Certification Requirements for Health IT Developers (Subpart D)

2.4.1 Assurances Condition of Certification

We have finalized updates to the Code of Federal Regulations (CFR) that do not create net new cost savings.

2.4.2 Application Programming Interfaces Condition of Certification

We have finalized updates to the CFR that do not create net new cost savings.

2.4.3 Real World Testing Condition of Certification

We have finalized as proposed revisions to the Real World Testing Condition of Certification that de-scope reporting requirements and codify what was previously guidance for the Certification Program and an exercise of enforcement discretion for the Condition of Certification.⁷⁶ As finalized in the Cures Act Final Rule (85 FR 25642), real world testing would be applicable for specific criteria—at the time of finalization, 23 criteria in all. This deregulatory action revises the Real World Testing Condition of Certification to apply reporting to only the API criteria adopted by the Certification Program. This revision creates cost savings to developers of certified health IT, as developers would no longer be required to plan, collect, and report on real world testing results for the full originally finalized set of criteria. We explain below the rationale and methodology that informed the cost savings for these finalized revisions to real world testing.

The finalized revisions to real world testing would take effect beginning in 2027. Cost savings to developers for ongoing compliance are, therefore, estimated beginning in 2027. Any costs for 2024 and 2025 are considered sunk. Beginning in the 2026 reporting year, as permitted in the real world testing enforcement discretion, only developers of certified APIs would be required to report for real world testing, specifically developers who certify Health IT Modules to the standardized API for patient and population services certification criterion, § 170.315(g)(10).⁷⁷ Cost savings calculations beginning in 2027 reflect the decreased burden on developers of certified health IT to comply with the condition of certification minus requirements that remain in place for developers who certify Health IT Modules to the applicable API-based criteria.

As of the end of 2024, using publicly available Certification Program data, we calculated that 336 developers had submitted real world testing plans for 2025 collection and 2026 reporting.⁷⁸ That is 93 fewer developers required to report for real world testing than estimated in the Cures Act Final Rule—a decrease of about 19 developers per year.⁷⁹ Calculating developer exits during this time period, after the Cures Act Final Rule took effect and prior to this finalized rule's effective date, is important to assess the estimated number of developers expected to comply with the remaining real world testing requirements, as finalized.

Beginning in 2026, we calculated an expected count of developers who we estimated would be required to report for real world testing in 2026 and beyond. This count assumes attrition from the original count of developers required to report for real world testing as finalized in the Cures Act Final Rule, as we described above for years prior to 2026. But given the changed program dynamics, in that real world testing would be required only for developers of certified APIs, the attrition rate beyond 2026 is harder to estimate. Given that current requirements are applicable for over 20 criteria adopted in the Certification Program and our attrition rate is based on participant exits from the Certification Program (for developers who certify Health IT

Modules to any of these criteria), we assume that attrition rate is likely more profound than exits for developers of certified APIs alone. We therefore estimate a new rate of developers who would be required to report for real world testing in total (n=320), beginning in 2026.

In our RIA for the HTI-4 Final Rule (included in the FY2026 IPPS/LTCH PPS final rule (90 FR 36536) as an ancillary provision), we estimated that beginning in 2027, approximately 189 developers would certify an electronic prior authorization API. The 189 count is a proxy measure, representing our estimation of the number of developers that would certify Health IT Modules to the § 170.315(g)(10) certification criterion in 2027.

Given that the revised Real World Testing Condition of Certification would only be associated with developers of certified APIs, we estimate beginning in 2026 that approximately 189 developers would be subject to the revised real world testing requirements. We used this count (189) to determine the net number of developers who would have been required to report for real world testing under the original requirements (inclusive of those who would have reported § 170.315(g)(10) testing results under the original requirements).

At the end of 2024, of the 336 developers required to report for real world testing, 198 developers of Health IT Modules certified to the § 170.315(g)(10) certification criterion or 59% of all developers. Using this rate, we estimate that beginning in 2026, approximately 320 developers would be subject to real world testing requirements, as finalized by the Cures Act Final Rule.⁸⁰ In 2026, however, only 189 developers would be subject to revised real world testing requirements—our estimate of the number of developers who would be subject to revised real world testing requirements (API only). This considers some attrition but at a different rate than used for years prior to 2026, as explained above.

Total savings beginning in 2027 are considered consistent and do not decrease due to future unknown attrition; however, we consider these cost savings to be realized by developers when the revised requirements take effect. If they were to exit the Certification Program in a year beyond 2027, these are still cost savings to be realized today from requirements they do not need to meet in all future years.

Beginning in 2027, cost savings are calculated by totaling the cost to all

⁷⁷ <https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement>.

⁷⁸ <https://chpl.healthit.gov/>.

⁷⁹ <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>.

⁷⁶ <https://www.healthit.gov/topic/real-world-testing-condition-and-maintenance-certification-requirements-enforcement>.

⁸⁰ Formula: $189 / (1 - 0.41) = 320$.

developers who certify Health IT Modules to real world testing applicable certification criteria to meet current real world testing requirements as finalized in the Cures Act Final Rule and revised in subsequent rulemakings (the HTI–1 Final Rule and the HTI–4 Final Rule) and subtracting the remaining cost for developers of certified APIs to comply with revised real world testing requirements. We estimate that, per developer, the cost of collecting and reporting real world testing data on § 170.315(g)(10) would be on average \$4,400 annually. We estimate this by calculating the average cost per criterion to meet real world testing requirements as finalized by the Cures Act Final Rule (\$109,557/23 = \$4,763) and decrease that by the proposed eliminated effort to submit annual testing plans (estimated to be 8% of total annual testing effort).⁸¹ This is congruent with our methodology finalized in the HTI–4 Final Rule about the average per criterion cost to plan, collect, and report for real world testing.⁸² The total cost of the remaining requirement to test for § 170.315(g)(10) would be subtracted from the total original program cost, as finalized by the Cures Act Final Rule, to estimate this deregulatory action’s annual cost savings.

Beginning in 2027, we also assume that developers of certified APIs would need to meet requirements for § 170.315(g)(10), as well as for § 170.315(g)(31), (g)(32), and (g)(33), as finalized in the HTI–4 Final Rule.⁸³ Real world testing requirements for the certification criteria adopted in § 170.315(g)(31), (g)(32), and (g)(33) were finalized in the HTI–4 Final Rule and would be a net new cost minus revisions to real world testing for developers not to submit annual testing plans. Furthermore, we also updated real world testing requirements in the HTI–4 Final Rule to include the new § 170.315(b)(4) certification criterion, which created net new costs to developers for real world testing. This deregulatory action now removes the § 170.315(b)(4) real world testing requirement and so we also assess the cost savings from that revision beginning in 2027 as well.

For costs savings, beginning in 2027 and in perpetuity, we estimate that

together, (original real world testing costs + § 170.315(b)(4) costs) minus ((g)(10) + (g)(31) + (g)(32) + (g)(33) revised costs) equals the estimated annual undiscounted cost savings of \$33.6 million.

2.4.4 Attestations

We have finalized updates to the CFR that do not create net new cost savings.

2.4.5 Insights Condition of Certification

We have not finalized as proposed revisions to the Insights Condition of Certification. In the HTI–1 Final Rule (89 FR 1192), we finalized requirements for developers to report on the Insights Condition of Certification, a set of uniform measures collected and reported by developers of certified health IT about the performance of their certified technology.⁸⁴ Applicable developers would be required to begin data collection January 1, 2026, for “Year 1” measures, with results reported in July 2027 and with “Year 2” measures set to begin collection January 1, 2027. Effort to plan and develop capabilities for these finalized measures was estimated to begin after the effective date of the HTI–1 Final Rule in January 2024. Effort to plan and develop the measurement capabilities for measures required to be collected in 2026 (“Year 1”) would be completed by January 1, 2026, and effort to plan and develop the measurement capabilities for measures required to be collected for the first time in 2027 (“Year 2”) would be completed by January 1, 2027, etc. We estimated developers would face annual data collection and reporting costs beginning in 2026 and in perpetuity. As we finalized in the HTI–1 Final Rule, the large majority of costs to developers of certified health IT would be costs to plan and develop for initial data collection of the finalized measures (effort largely expended from 2024–2026 in our original analysis).

ONC exercised enforcement discretion in April 2025 with respect to Insights requirements except for a single measure—“Use of FHIR”—a “Year 1” measure.⁸⁵ We have finalized proposed revisions to the Insights Condition of Certification with one change to the proposal. In this final rule, in addition

to retaining requirements for applicable developers of certified health IT to collect data on and report the “Use of FHIR” measure, we did not finalize our proposal to remove the “Use of Bulk FHIR” measure. Therefore, developers will continue to be required to collect data on and report on the “Use of Bulk FHIR” measure. We explain below the rationale and methodology that informed the cost savings for these proposed revisions to Insights.

To calculate cost savings associated with the proposed revisions to the Insights Condition of Certification, we subtracted the estimated amount for developers to report for the remaining two Insights measures (“Use of FHIR” and “Use of Bulk FHIR”) from the estimated cost for developers to meet the Insights Condition of Certification, as finalized in the HTI–1 Final Rule. In Table 35 of the HTI–1 Final Rule, we estimated that the upper bound cost for all developers to report on the “Use of FHIR” and “Use of Bulk FHIR” measures over a ten-year period was \$72.8 million.⁸⁶ The total upper bound cost to report on all measures for all developers over a ten-year period was \$218.7 million. Therefore, we estimate the measures to be 34% of all estimated Insights costs.

In Table R–4 we show the undiscounted revised cost savings for the finalized changes to the Insights Condition of Certification. We estimated, on average, that the HTI–1 Final Rule costs for Insights would be \$158.5 million. We estimated that the cost for developers to begin implementing Insights in 2024 (toward effort to collect and report on measures in 2026 and 2027) would on average, total \$46.4 million. This included initial planning and development costs for all measures with more assumed effort toward completing work to prepare for “Year 1” measures set to begin collection January 1, 2026. We consider these costs as sunk. The Insights enforcement discretion, however, reduced effort for ongoing planning and development work for 2025 and after. We include the reduced effort to meet these requirements in years 2027 and after to be a net cost savings to developers, as Table R–4 shows. The total undiscounted cost savings, beginning in 2025, are \$73.3 million (Table R–4).

⁸¹ Formula: $\$4,763 \times (1 - 0.08) = \$4,382$.

⁸² <https://www.federalregister.gov/d/2025-14681/p-7025>.

⁸³ <https://www.federalregister.gov/documents/2025/08/04/2025-14681/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-ipp-and>.

⁸⁴ <https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and>.

⁸⁵ <https://www.healthit.gov/topic/insights-condition-and-maintenance-certification-enforcement-discretion>.

⁸⁶ <https://www.federalregister.gov/d/2023-28857/p-2641>.

Table R-4: Revised Insights Undiscounted Cost Savings

Year	Total
2024	\$0
2025	\$31,086,023
2026	\$17,104,295
2027	\$11,777,922
2028-2033	\$13,398,082
Total-Undiscounted	\$73,366,323

b. Accounting Statement and Table

This finalized rule is an E.O. 14192 deregulatory action. The finalized policies remove or reduce requirements on developers of certified health IT. No finalized policies create net new requirements or additional burden to comply with existing requirements. However, we do estimate some costs for reviewers who review this rule. We estimate those costs to be \$1,293,508 in total for 616 reviewers. As articulated in the preamble, these finalized deregulatory actions reduce the effort of developers of certified health IT to meet ongoing program requirements and reduce barriers to entry for new program participants, generating benefits to developers of certified health IT in the

form of time back to them to innovate their technology and focus on the needs of their clients and end users. We do not, however, quantify these benefits, and instead rely on our calculation of cost savings to developers of certified health IT to quantify in dollars the time and effort developers would have expended had these requirements remained in effect in perpetuity. We estimate that these proposals do generate significant cost savings for developers of certified health IT.

To calculate the cost savings associated with this finalized rulemaking, we replicate the analysis of prior finalized rulemakings and align those with current data, adopting, where necessary, novel methodologies and

models to assess the current costs to developers of certified health IT of the finalized revisions to the Certification Program. As shown in Table R-5, we present the undiscounted cost savings over ten years and in Table R-6 we present the discounted cost savings associated with these finalized policies for ten years. In Table R-6, we adopt a 3% and 7% discount rate consistent with Circular A-4 (2003).⁸⁷ In total, consistent with analytic guidance on E.O. 14192, this finalized rulemaking would result in a present value of cost savings of \$1.55 billion and annualized net cost savings of \$108.1 million in 2024 dollars and discounted at a rate of 7%, beginning in 2027 and in perpetuity as shown in Table R-7.⁸⁸

Table R-5: EO 12866 Summary Table Non-Discounted Flows (2024 Dollars)					
	Year 1	Year 2	Year 3	Year 4	Year 5
Costs	\$ 1,293,508	\$ 0	\$ 0	\$ 0	\$ 0
Cost Savings	\$ 134,801,967	\$ 125,257,059	\$ 125,257,059	\$ 138,129,849	\$ 138,129,849
	Year 6	Year 7	Year 8	Year 9	Year 10
Costs	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0
Cost Savings	\$ 138,129,849	\$ 138,129,849	\$ 138,129,849	\$ 138,129,849	\$ 138,129,849

⁸⁷ <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>.
⁸⁸ <https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf>.

Table R-6. EO 12866 Summary Table (2024 Dollars)		
	Primary (3%)	Primary (7%)
Present Value of Quantified Costs	\$ 1,255,833	\$ 1,208,886
Present Value of Quantified Cost Savings	\$ 1,151,130,412	\$ 945,304,464
Present Value of Net Cost Savings	\$ 1,149,874,579	\$ 944,095,578
	Primary (3%)	Primary (7%)
Annualized Quantified Costs	\$ 147,222	\$ 172,118
Annualized Quantified Cost Savings	\$ 134,947,601	\$ 134,590,089
	Primary (3%)	Primary (7%)
Annualized Net Quantified Cost Savings	\$ 134,800,379	\$ 134,417,917

Table R-7. EO 14192 Summary Table (2024 Dollars)	
	Primary (7%)
Present Value of Quantified Costs	\$ 1,208,886
Present Value of Quantified Cost Savings	\$ 1,545,804,005
Present Value of Net Cost Savings	\$ 1,544,546,064
	Primary (7%)
Annualized Quantified Costs	\$ 172,118
Annualized Quantified Cost Savings	\$ 108,206,280
	Primary (7%)
Annualized Net Quantified Cost Savings	\$ 108,118,224

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) 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. The Small Business Administration (SBA) establishes the size of small businesses for Federal Government programs based on average annual receipts or the average employment of a firm.⁸⁹

The entities that are likely to be directly affected by the requirements in this finalized rule are health IT developers.

⁸⁹ The SBA references that annual receipts mean “total income” (or in the case of a sole proprietorship, “gross income”) plus “cost of goods sold” as these terms are defined and reported on Internal Revenue Service tax return forms.

While health IT developers that pursue certification of their health IT under the Certification Program represent a small segment of the overall information technology industry, we believe that many health IT developers impacted by the requirements in this final rule most likely fall under the North American Industry Classification System (NAICS) code 513210 “Software Publishers.”

OMB advised that the Federal statistical establishment data published for reference years beginning on or after January 1, 2022, should be published using the 2022 NAICS United States codes.⁹⁰ The SBA size standard associated with this NAICS code is set

⁹⁰ <https://www.sba.gov/article/2022/feb/01/guidance-using-naics-2022-procurement>.

at \$47 million annual receipts or less. There is enough data generally available to establish that over 90% of entities that are categorized under the NAICS code 513210 are under the SBA size standard. We also note that with the exception of aggregate business information available through the U.S. Census Bureau and the SBA related to NAICS code 513210, it appears that many health IT developers that pursue certification of their health IT under the Certification Program are privately held or owned and do not regularly, if at all, make their specific annual receipts publicly available. As a result, it is difficult to locate empirical data related to many of these health IT developers to correlate to the SBA size standard. However, HHS program data provide approximate counts of health care

providers who use specific certified Health IT Modules.^{91 92 93} In combination with public market research about the average annual cost of a hospital or physician licensing an EHR, we can estimate projected annual receipts for each developer of certified health IT and determine if they are under the \$47 million threshold.^{94 95}

Using a licensing cost of \$15,000 per bed for hospital customers and \$8,000 per provider for ambulatory practice sites, we multiplied these amounts by the number of hospital beds and ambulatory providers who report use of each developer's certified health IT. We then increased the number of ambulatory providers who report each developer by 50% to reflect that the Medicare Promoting Interoperability is not fully representative of the full outpatient provider population and that data alone may undercount developers' true customer base. Additional customer data available via public API endpoint lists were used to adjust estimates of each developer's customer counts. We also considered per customer licensing fees as only a 75% share of each developer's projected annual receipts. Therefore, based on this methodology, any developer with projected licensing revenue less than \$35.25 million was considered a small business. Among 466 developers, we estimate that approximately 64 (or 14%) are not considered small businesses. We, therefore, estimate that approximately 86% of developers of certified health IT are small businesses, close to the overall industry estimate of "Software Publishers" (90%).

With the exception of rule review costs, this finalized rulemaking is deregulatory and does not create new requirements on developers of certified health IT, including small businesses. We believe the finalized deregulatory actions will create net cost savings for developers and would create a significant positive economic impact on small entities who participate directly in the Certification Program as a developer of certified health IT or as an entity who interoperates with certified health IT. Finalized revisions reduce burdens on small developers to meet ongoing reporting and documentation

requirements, as well as support for redundant standards and functionalities—which can weigh heavier on smaller developers with smaller developer and engineering teams. As the finalized revisions largely reflect reduced effort to meet annual reporting, other recurring program requirements, and ongoing maintenance of Health IT Modules, we assume the projected cost savings in this final rule may be shared equally across developers, both small and large. This means that up to 86% of cost savings (or \$93 million annualized net quantified cost savings) could be realized by small developers of certified health IT.

In the proposed rule, we requested comment on whether there are small entities that currently pursue certification of health IT under the Certification Program (and how many); what products they certify; whether there are any negative or unintended costs for small entities from the proposals included in this rule; and whether small entities will significantly benefit from the proposals included in this rule. We received no comments in response.

D. Executive Order 13132—Federalism

E.O. 13132 establishes certain requirements that an agency must meet when it promulgates a finalized rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Nothing in this finalized rule imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We are not aware of any State laws or regulations that are contradicted or impeded by any of the policies in this finalized rule. We welcomed comments on this assessment and received no response.

E. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that imposes unfunded mandates on State, local, and Tribal governments or the private sector requiring spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately \$187 million in 2025. This finalized rule is deregulatory, and, therefore, the estimated potential cost effects of this finalized rule do not reach the statutory threshold. This finalized rule does not impose unfunded mandates on State,

local, and Tribal governments, or the private sector.

Comments. Multiple commenters expressed concern that our proposals impose unfunded mandates on State, local, and tribal governments and the private sector. Commenters were concerned that de-regulation shifts the burden of assessing health IT functionality and standards adoption to end users. Two commenters expressed their concerns specifically with the downstream effects of our public health-related proposals (§ 170.315(f)(4), § 170.315(f)(5), § 170.315(f)(6) and § 170.315(f)(7)) which sought to remove the standards-based requirements for electronic case reporting and antimicrobial use and resistance reporting and remove the requirements to support cancer registry reporting and creation of health care survey information.

Response. We thank commenters for their input. The changes in § 170.315(f)(4), § 170.315(f)(5), and § 170.315(f)(7) have not been finalized as proposed—we are maintaining requirements to support cancer registry reporting and creation of health care survey information and keeping electronic case reporting as a standards-based criterion. We have finalized as proposed the removal of standards-based requirements in § 170.315(f)(6), which have not kept pace with reporting requirements and therefore we believe this change will not impose downstream costs on end-users to submit AUR data NHSN. Given these final decisions, we do not anticipate any significant downstream costs or burdens to be shifted on public health entities. In response to broader concerns that our proposals impose unfunded mandates or that de-regulation shifts the burden of assessing health IT and standards adoption to end users, we have chosen to finalize 14 of 34 criteria proposed for removal from the CFR, with many of those removals consisting of criteria with low adoption rates overall. Furthermore, the reduced scope of conditions and maintenance of certification reflect the prioritization of reporting and documentation requirements to focus developer efforts on API criteria and associated requirements, as these are less mature and evolving requirements which necessitate focused developer efforts to monitor and evaluate these functionalities in real world settings. These are necessary program improvements that will enhance the overall performance of the Certification Program and allow it to evolve to meet emerging needs that will benefit the nation as a whole.

⁹¹ <https://healthit.gov/data/datasets/certified-health-information-technology-reported-clinicians-promoting/>.

⁹² <https://healthit.gov/data/datasets/certified-health-information-technology-reported-by-hospitals-for-promoting-interoperability-performance/>.

⁹³ <https://chpl.healthit.gov/#/api-documentation>.

⁹⁴ <https://www.practiceehr.com/blog/how-much-does-ehr-software-cost-pricing>.

⁹⁵ <https://softwarefinder.com/resources/cost-to-implement-a-top-emr>.

List of Subjects**45 CFR Part 170**

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and record keeping requirements, Public health, Security.

45 CFR Part 172

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health information technology, Health insurance, Health records, Hospitals, Laboratories, Medicaid, Medicare, Privacy, Public health, Security.

For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, is amended as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 2. Amend § 170.102 by:

■ a. In the definition of “Base EHR”:

■ i. Revising paragraph (3)(i); and

■ ii. Removing and reserving paragraphs (3)(ii) and (iii); and

■ b. Removing definition for “Common Clinical Data Set”.

The revision reads as follows:

§ 170.102 Definitions.

* * * * *

Base EHR * * *

(3) * * *

(i) Section 170.315(a)(1), (2), or (3), (a)(5) and (14), (b)(1) and (11), (c)(1), and (g)(10).

* * * * *

§ 170.202 [Amended]

■ 3. Amend § 170.202 by removing and reserving paragraphs (b), (c), and (e).

§ 170.204 [Removed and Reserved]

■ 4. Remove and reserve § 170.204.

■ 5. Amend § 170.205 by:

■ a. Revising paragraph (d)(2); and

■ b. Removing and reserving paragraphs (k)(1) and (2) and (r).

The revision reads as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * * *

(d) * * *

(2) *Standard.* HL7 2.5.1 (Messaging Standard; incorporated by reference in § 170.299).

* * * * *

§ 170.207 [Amended]

■ 6. Amend § 170.207 by:

■ a. Removing paragraphs (a)(4) and (c)(3);

■ b. Removing and reserving paragraphs (d)(1)(ii) and (iii);

■ c. Removing paragraphs (e)(3) and (4); and

■ d. Removing and reserving paragraphs (f)(2) and (m)(1).

§ 170.207 [Amended]

■ 7. Effective January 1, 2027, further amend § 170.207 by removing paragraphs (r) and (s).

§ 170.215 [Amended]

■ 8. Amend § 170.215 by removing and reserving paragraphs (b)(1)(i) and (c)(1).

■ 9. Revise and republish § 170.299 to read as follows:

§ 170.299 Incorporation by reference.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the U.S. Department of Health and Human Services (HHS) and at the National Archives and Records Administration (NARA). Contact HHS at: U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201; call ahead to arrange for inspection at (202) 690–7151. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the following sources:

(a) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; phone (610) 832–9585; website www.astm.org/.

(1) ASTM E2147–18 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, approved May 1, 2018; IBR approved for § 170.210(h).

(2) [Reserved]

(b) Centers for Disease Control and Prevention, 2500 Century Parkway, Mailstop E–78, Atlanta, GA 30333;

phone: (800) 232–4636; website: www.cdc.gov/cdc-info/index.html.

(1) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012; IBR approved for § 170.205(g).

(2) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015; IBR approved for § 170.205(d).

(3) Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings; IBR approved for § 170.205(d).

(4) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 1, 2014; IBR approved for § 170.205(e).

(5) HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015; IBR approved for § 170.205(e).

(6) HL7® Standard Code Set CVX—Vaccines Administered, dated June 15, 2022; IBR approved for § 170.207(e).

(7) National Drug Code Directory (NDC)—Vaccine NDC Linker, dated July 19, 2022; IBR approved for § 170.207(e).

(8) CDC Race and Ethnicity Code Set version 1.2 (July 08, 2021); IBR approved for § 170.207(f).

(c) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; phone: (410) 786–3000; website: www.cms.gov.

(1) CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting Implementation Guide for 2020; published December 3, 2019; IBR approved for § 170.205(h).

(2) CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs Implementation Guide for 2020; published April 30, 2020; IBR approved for § 170.205(k).

(3) Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy; April 2, 2015, IBR approved for § 170.207(r).

(4) Medicare Provider and Supplier Taxonomy Crosswalk, 2021; IBR approved for § 170.207(r).

(d) Council of State and Territorial Epidemiologists, 2635 Century Parkway NE, Suite 700, Atlanta, GA 30345; phone: (770) 458–3811; website: www.cste.org/.

(1) Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting, RCTC OID:

2.16.840.1.114222.4.11.7508, Release March 29, 2022; IBR approved for § 170.205(t).

(2) [Reserved]

(e) Health Level Seven, 455 E Eisenhower Parkway, Suite 300 #025, Ann Arbor, MI 48108; phone: (734) 677-7777; website: www.hl7.org/.

(1) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007; IBR approved for § 170.205(d).

(2) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU-R01, HL7 Informative Document, February 2010; IBR approved for § 170.205(g).

(3) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012; IBR approved for § 170.205(a).

(4) HL7 Clinical Document Architecture, Release 2.0, Normative Edition, May 2005; IBR approved for § 170.205(i).

(5) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September 29, 2011; IBR approved for § 170.205(g).

(6) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1, August 2015; IBR approved for § 170.205(a).

(7) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1, August 2015; IBR approved for § 170.205(a).

(8) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1—Introductory Material, June 2015; IBR approved for § 170.205(h).

(9) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2—Templates and Supporting Material, June 2015; IBR approved for § 170.205(h).

(10) HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 1—Introductory Material, April 2015; IBR approved for § 170.205(i).

(11) HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 2—Templates and Supporting Material, April 2015; IBR approved for § 170.205(i).

(12) HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, Part 1: CDA R2 and Privacy Metadata Reusable Content Profile, May 16, 2014; IBR approved for § 170.205(o).

(13) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material, December 2014; IBR approved for § 170.205(s).

(14) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, December 2014; IBR approved for § 170.205(s).

(15) HL7 Version 3 (V3) Standard, Value Sets for Administrative Gender and Null Flavor, published August 1, 2013; IBR approved for § 170.207(n) and (o).

(16) HL7® CDA® R2 Implementation Guide: C—CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2—US Realm, October 2019; IBR approved for § 170.205(a).

(17) HL7 FHIR® Bulk Data Access (Flat FHIR®) (v1.0.0: STU 1), August 22, 2019; IBR approved for § 170.215(a).

(18) HL7 Fast Healthcare Interoperability Resources Specification (FHIR®) Release 4, Version 4.0.1: R4, October 30, 2019, including Technical Correction #1, November 1, 2019; IBR approved for § 170.215(a).

(19) HL7 CDA® R2 Implementation Guide: C—CDA Templates for Clinical Notes STU Companion Guide, Release 4.1 (US Realm) Standard for Trial Use, Specification Version: 4.1.1, June 2023 (including appendices A and B); IBR approved for § 170.205(a).

(20) HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR)—US Realm, Version 2.1.0—STU 2 US (HL7 FHIR eCR IG), August 31, 2022; IBR approved for § 170.205(t).

(21) HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7 CDA eICR IG), July 2022, volumes 1 and 2; IBR approved for § 170.205(t).

(22) HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1—US Realm (HL7 CDA RR IG), July 2022, volumes 1

through 4; IBR approved for § 170.205(t).

(23) HL7 FHIR US Core Implementation Guide Version 6.1.0—STU 6, June 19, 2023; IBR approved for § 170.215(b).

(24) HL7 FHIR® SMART App Launch [Implementation Guide], 2.0.0—Standard for Trial Use, November 26, 2021; IBR approved for § 170.215(c).

(25) HL7 FHIR® Da Vinci—Coverage Requirements Discovery IG [Implementation Guide], Version 2.2.1—STU 2.2, Generated March 27, 2026; IBR approved for § 170.215(j).

(26) HL7 FHIR® Da Vinci—Documentation Templates and Rules Implementation Guide, Version 2.2.0—STU 2.2, Generated March 27, 2026; IBR approved for § 170.215(j).

(27) HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.2.1—STU 2.2, Generated March 27, 2026; IBR approved for § 170.215(j).

(28) HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) [Implementation Guide], Version 2.2.0—STU 2.2, Generated March 27, 2026; IBR approved for § 170.215(k).

(29) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1, June 18, 2025; IBR approved for § 170.215(k).

(30) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.1.0—STU 2.1, Generated February 26, 2025; IBR approved for § 170.215(m).

(31) HL7 FHIR® Da Vinci PDex [Payer Data Exchange] Plan Net Implementation Guide, Version 1.2.0—STU 1.2, Generated February 25, 2025; IBR approved for § 170.215(n).

(32) HL7 FHIR® Subscriptions R5 Backport Implementation Guide, Version 1.1.0—Standard for Trial Use, draft as of January 11, 2023; IBR approved for § 170.215(h).

(33) HL7 FHIR® CDS Hooks Implementation Guide, Version 2.0.1—STU 2 Release 2, March 12, 2025; IBR approved for § 170.215(f).

(34) HL7 FHIR® Da Vinci Clinical Data Exchange (CDex) IG [Implementation Guide], Version 2.1.0—STU 2.1, Generated February 11, 2025; IBR approved for § 170.215(k).

(g) Integrating the Healthcare Enterprise (IHE), 820 Jorie Boulevard, Oak Brook, IL; phone: (630) 481-1004; website: www.ihe.net/.

(1) IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b), Transactions Part B—Sections 3.29—3.43, Revision 7.0, August 10, 2010; IBR approved for § 170.205(p).

(2) [Reserved]

(h) Internet Engineering Task Force (IETF), IETF Administration LLC, 1000 N West Street, Suite 1200, Wilmington, DE 19801, phone (302) 319–3421; email: support@ietf.org; website: www.ietf.org/.

(1) Request for Comment (RFC) 5646, Tags for Identifying Languages, September 2009, copyright 2009; IBR approved for § 170.207(g).

(2) [Reserved]

(i) International Telecommunication Union (ITU), Place des Nations, 1211 Geneva 20 Switzerland; phone: (41) 22 730 511; website: www.itu.int/en/pages/default.aspx.

(1) ITU–T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—General provisions concerning users: Notation for national and international telephone numbers, email addresses and web addresses, February 2001; IBR approved for § 170.207(q).

(2) ITU–T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—Numbering plan of the international telephone service, The international public telecommunication numbering plan, November 2010; IBR approved for § 170.207(q).

(j) National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E Raintree Drive, Scottsdale, AZ 85260–7518; phone (480) 477–1000; fax: (480) 767–1042; website: www.ncdp.org.

(1) NCPDP SCRIPT Standard, Implementation Guide, Version 2017071, ANSI-approved July 28, 2017; IBR approved for § 170.205(b).

(2) NCPDP SCRIPT Standard, Implementation Guide, Version 2023011, ANSI-approved January 17, 2023; IBR approved for § 170.205(b).

(3) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, ANSI-approved May 19, 2022; IBR approved for § 170.205(c).

(4) NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60, ANSI-approved April 12, 2023; IBR approved for § 170.205(u).

(k) National Institute of Standards and Technology (NIST), Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930; website <https://csrc.nist.gov/projects/cryptographic-module-validation-program>.

(1) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010; IBR approved for § 170.210.

(2) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, May 30, 2012; IBR approved for § 170.210.

(3) FIPS PUB 180–4, Secure Hash Standard (August 2015); IBR approved for § 170.210(c).

(l) Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW, Washington, DC 20201; phone: (202) 690–7151; website: <https://healthit.gov>.

(1) United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata; IBR approved for § 170.213. (Available at https://isp.healthit.gov/sites/default/files/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf.)

(2) United States Core Data for Interoperability (USCDI), Version 3 (v3), October 2022 Errata; IBR approved for § 170.213.

(3) ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014, IBR approved for § 170.202(d); available at http://www.healthit.gov/sites/default/files/implementationguidefordirectedgeprotocolsv1_1.pdf.

(m) Regenstrief Institute, Inc., LOINC® c/o Regenstrief Center for Biomedical Informatics, Inc., 410 West 10th Street, Suite 2000, Indianapolis, IN 46202–3012; phone: (317) 274–9000; website: <https://loinc.org/> and <https://ucum.org/ucum>.

(1) Logical Observation Identifiers Names and Codes (LOINC®) Database Version 2.72, February 2022; IBR approved for § 170.207(c).

(2) The Unified Code for Units of Measure, Version 2.1, November 21, 2017; IBR approved for § 170.207(m).

(n) The Direct Project, c/o the Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW, Washington, DC 20201; email: ONC.Request@hhs.gov; website: <https://healthit.hhs.gov>.

(1) Applicability Statement for Secure Health Transport, Version 1.2, August 2015; IBR approved for § 170.202(a).

(2) [Reserved]

(o) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; phone (301) 594–5983; website: www.nlm.nih.gov/.

(1) SNOMED CT® [SNOMED Clinical Terms] U.S. Edition, March 2022 Release; IBR approved for § 170.207(a).

(2) RxNorm, December 4, 2023, Full Update Release; IBR approved for § 170.207(d).

(p) Public Health Data Standards Consortium, 111 South Calvert Street, Suite 2700, Baltimore, MD 21202; phone: (801) 532–2299; website: www.nahdo.org/sopt.

(1) Public Health Data Standards Consortium Source of Payment

Typology Code Set Version 5.0 (October 2011); IBR approved for § 170.207(s).

(2) Users Guide for Source of Payment Typology, Version 9.2, December 2020; IBR approved for § 170.207(s).

§ 170.299 [Amended]

■ 10. Effective January 1, 2027, amend § 170.299 by removing paragraphs (c)(3) and (4) and (p).

■ 11. Amend § 170.315 by:

■ a. Removing and reserving paragraph (a)(9);

■ b. Revising paragraphs (b)(1)(i) introductory text, (b)(1)(ii), (b)(1)(iii) introductory text, and (b)(2);

■ c. Removing and reserving paragraphs (b)(7) through (9);

■ d. Removing paragraph (b)(11)(ii)(B);

■ e. Redesignating paragraph (b)(11)(ii)(C) as paragraph (b)(11)(ii)(B);

■ f. Revising paragraphs (b)(11)(iii) introductory text and (b)(11)(iii)(B);

■ g. Removing paragraphs (b)(11)(iv) through (vi);

■ h. Revising paragraph (c)(3);

■ i. Revising and republishing paragraph (e)(1);

■ j. Revising paragraphs (f)(6) and (g)(3); and

■ k. Removing and reserving paragraphs (g)(6) and (h).

The revisions and republication read as follows:

§ 170.315 ONC certification criteria for Health IT.

* * * * *

(b) * * *

(1) * * *

(i) *Send and receive via edge protocol.*

The requirements in this paragraph

(b)(1)(i) expire on January 1, 2030.

* * * * *

(ii) *Validate and display—(A) Validate C–CDA conformance—system performance.* Demonstrate the ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with the standards specified in § 170.205(a)(4) and (6) for the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates. This includes the ability to:

(1) Parse each of the document types.

(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in the standards adopted in § 170.205(a)(4) and (6).

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in § 170.205(a)(4) and (6).

(4) Correctly interpret empty sections and null combinations.

(5) Record errors encountered and allow a user through at least one of the following ways to:

(i) Be notified of the errors produced.

(ii) Review the errors produced.

(B) *Display*. Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(4) and (6). The requirements in this paragraph (b)(1)(ii)(B) expire on January 1, 2030.

(C) *Display section views*. Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in § 170.205(a)(4) and (6) in a manner that enables the user to do the following. The requirements in this paragraph (b)(1)(ii)(C) expire on January 1, 2030.

(1) Directly display only the data within a particular section;

(2) Set a preference for the display order of specific sections; and

(3) Set the initial quantity of sections to be displayed.

(iii) *Create*. Enable a user to create a transition of care/referral summary formatted in accordance with the standard specified in § 170.205(a)(4) and (6) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum the following. The requirements in this paragraph (b)(1)(iii) expire on January 1, 2030.

(2) *Clinical information reconciliation and incorporation*. Technology must demonstrate the following, in at least one applicable workflow, which could include upon receipt of a transition of care/referral summary:

(i) Properly match information received from another source with the correct patient for whom the information is intended to be reconciled.

(ii) Create a single reconciled list of each of the following: Medications, Allergies and Intolerances, and Problems.

(iii) Enable a user to review and validate the accuracy of a final set of data.

(iv) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standards:

(A) Medications. At a minimum, the version of the standard specified in § 170.213;

(B) Allergies and intolerance. At a minimum, the version of the standard specified in § 170.213; and

(C) Problems. At a minimum, the version of the standard specified in § 170.213.

* * * * *

(11) * * *

(iii) *Decision support intervention selection*. Enable a limited set of identified users to select (*i.e.*, activate) electronic decision support interventions that are:

* * * * *

(B) Predictive Decision Support Interventions and use any data in paragraph (b)(11)(iii)(A) of this section as well as Clinical Notes and Assessment and Plan of Treatment expressed in the standards for this data in § 170.213.

(c) * * *

(3) *Clinical quality measures—report*. Enable a user to electronically create a data file for transmission of clinical quality measurement data in accordance with the applicable implementation specifications specified by the CMS implementation guides for Quality Reporting Document Architecture (QRDA), Category I, for inpatient measures in § 170.205(h)(3) and CMS implementation guide for QRDA, Category III for ambulatory measures in § 170.205(k)(3).

* * * * *

(e) * * *

(1) *View, download, and transmit to 3rd party—(i) General*. Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified in this paragraph (e)(1)(i).

(A) *View*. Patients (and their authorized representatives) must be able to use health IT to view, at a minimum, the following data:

(1) [Reserved]

(2) The data classes expressed in the standards in § 170.213 (which should be in their English (*i.e.*, non-coded) representation if they associate with a vocabulary/code set), and in accordance with § 170.205(a)(4) and (6), and paragraphs (e)(1)(i)(A)(3)(i) through (iii) of this section.

(3) The following data classes:

(i) *Assessment and plan of treatment*. In accordance with the “Assessment and Plan Section (V2)” of the standard specified in § 170.205(a)(4); or in accordance with the “Assessment Section (V2)” and “Plan of Treatment Section (V2)” of the standard specified in § 170.205(a)(4).

(ii) *Goals*. In accordance with the “Goals Section” of the standard specified in § 170.205(a)(4).

(iii) *Health concerns*. In accordance with the “Health Concerns Section” of the standard specified in § 170.205(a)(4).

(iv) *Unique device identifier(s) for a patient's implantable device(s)*. In accordance with the “Product Instance” in the “Procedure Activity Procedure Section” of the standards specified in § 170.205(a)(4).

(4) For ambulatory settings only provider's name and office contact information.

(5) For inpatient settings only: admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(6) Laboratory test report(s), including:

(i) The information for a test report as specified in 42 CFR 493.1291(c)(1) through (7);

(ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

(iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).

(7) Diagnostic image report(s).

(B) *Download*. (1) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in the following formats:

(i) Human readable format; and

(ii) The format specified in accordance with the standard specified in § 170.205(a)(4) and (6) and following the CCD document template.

(2) When downloaded according to the standard specified in § 170.205(a)(4) and (6) following the CCD document template, the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(i) *Ambulatory setting only*. All of the data specified in paragraphs (e)(1)(i)(A)(1), (2), (4), and (5) of this section.

(ii) *Inpatient setting only*. All of the data specified in paragraphs (e)(1)(i)(A)(1) and (3) through (5) of this section.

(3) Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion specified in paragraph (b)(1) of this section).

(C) *Transmit to third party.* Patients (and their authorized representatives) must be able to:

(1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with both of the following ways:

(i) Email transmission to any email address; and

(ii) An encrypted method of electronic transmission.

(2) Transmit transition of care/referral summaries (as a result of a transition of care/referral as referenced by paragraph (e)(1)(i)(B)(3) of this section) of this section selected by the patient (or their authorized representative) in both of the ways referenced in paragraphs (e)(1)(i)(C)(1)(i) and (ii) of this section).

(D) *Timeframe selection.* With respect to the data available to view, download, and transmit as referenced paragraphs (e)(1)(i)(A) through (C) of this section, patients (and their authorized representatives) must be able to:

(1) Select data associated with a specific date (to be viewed, downloaded, or transmitted); and

(2) Select data within an identified date range (to be viewed, downloaded, or transmitted).

(ii) *Activity history log.* (A) When any of the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section are used, the following information must be recorded and made accessible to the patient (or his/her authorized representative):

(1) The action(s) (*i.e.*, view, download, transmission) that occurred;

(2) The date and time each action occurred;

(3) The user who took the action; and

(4) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) [Reserved]

(iii) *Request for restrictions.* Patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied for any data expressed in the standards in § 170.213. Conformance with this paragraph is required by January 1, 2026.

* * * * *

(f) * * *

(6) *Transmission to public health agencies—antimicrobial use and resistance reporting.* Create antimicrobial use and resistance reporting information for electronic transmission.

* * * * *

(g) * * *

(3) *Safety-enhanced design.* (i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (5), and (14) and (b)(2), (3), and (11) of this section.

(ii) One of the following must be submitted on the user-centered design process used:

(A) Name and/or publication citation for an industry or Federal Government standard.

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

* * * * *

§ 170.315 [Amended]

■ 12. Effective January 1, 2027, further amend § 170.315 by removing and reserving paragraphs (a)(12), (c)(4), (e)(3), and (g)(1), (2), (7), and (9).

■ 13. Amend § 170.402 by

■ a. Revising paragraph (b)(2); and

■ b. Removing paragraph (b)(4).

The revision reads as follows:

§ 170.402 Assurances.

* * * * *

(b) * * *

(2) A health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10).

* * * * *

■ 14. Amend § 170.404 by:

■ a. Revising the introductory text and paragraph (b)(2) introductory text;

■ b. Removing paragraphs (b)(3) and (4); and

■ c. Revising the definition for “Certified API technology” in paragraph (c).

The revisions read as follows:

§ 170.404 Application programming interfaces.

The following Condition and Maintenance of Certification requirements apply to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(10) and (31) through (33) unless otherwise specified in this section.

* * * * *

(b) * * *

(2) *Service base URL publication.* For all Health IT Modules certified to § 170.315(g)(10), a Certified API Developer must publish, at no charge,

the service base URLs and related organization details that can be used by patients to access their electronic health information. This includes all customers regardless of whether the Health IT Modules certified to § 170.315(g)(10) are centrally managed by the Certified API Developer or locally deployed by an API Information Source. These service base URLs and organization details must conform to the following:

* * * * *

(c) * * *

Certified API Technology means the capabilities of Health IT Modules that are certified to any of the API-focused certification criteria adopted in § 170.315(g)(10), (31), (32), and (33).

■ 15. Amend § 170.405 by:

■ a. Revising paragraph (a);

■ b. Removing and reserving paragraph (b)(1);

■ c. Revising and republishing paragraph (b)(2); and

■ d. Revising paragraph (b)(8) introductory text.

The revisions and republication read as follows:

§ 170.405 Real world testing.

(a) *Condition of Certification requirement.* A health IT developer with one or more Health IT Module(s) certified to any one or more of the Certification Criteria for Health IT in § 170.315(b), (c), (e), (f), (g)(10) and (31) through (33), and (j) must, on an annual basis, successfully test the real world use of those Health IT Module(s) for interoperability (as defined in 42 U.S.C. 300jj(9) and § 170.102) in the type of setting in which such Health IT Module(s) would be/is marketed.

(b) * * *

(2) *Real world testing results reporting.* (i) If in the course of

conducting real world testing the developer discovers one or more non-conformities with the full scope of any certification criterion under the Program, the developer must report that non-conformity to the ONC-ACB within 30 days.

(ii) For real world testing activities conducted during the immediately preceding calendar year, a health IT developer must submit to its ONC-ACB an annual real world testing results report that:

(A) Addresses each of its certified Health IT Modules that were certified to, including through Inherited Certified Status, the § 170.315(g) certification criteria referenced in paragraph (a) of this section in the year preceding the real world testing calendar year reporting period;

(B) Includes the newer versions of certified Health IT Modules that include

the § 170.315(g) certification criteria referenced in paragraph (a) of this section that were updated using Inherited Certified Status during the real world testing reporting period; and

(C) Is submitted by a date determined by the ONC-ACB that enables the ONC-ACB to publish a publicly available hyperlink to the results report on the CHPL no later than March 15 of each calendar year, beginning in 2023.

(iii) The real world testing results must report the following for each of the § 170.315(g) certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

(A) The method(s) that was used to demonstrate real world interoperability;

(B) The care setting(s) that was tested for real world interoperability;

(C) The voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process;

(D) A list of the key milestones met during real world testing;

(E) The outcomes of real world testing including a description of any challenges encountered during real world testing; and

(F) At least one measurement/metric associated with the real world testing.

(iv) For each Health IT Module certified to any certification criterion specified in paragraph (a) of this section, other than the § 170.315(g) certification criteria (see paragraph (b)(2)(iii) of this section for requirements), identify the voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process.

* * * * *

(8) *Standards Version Advancement Process—voluntary updates of certified health IT to newer versions of standards and implementation specifications.* A health IT developer of certified health IT subject to paragraph (a) of this section is permitted to update Health IT Module(s) certified to any one or more of the certification criteria referenced in paragraph (a) of this section to a newer version of any adopted standard or implementation specification included in the criterion, provided that newer version is approved by the National Coordinator for use in certifications issued under the ONC Health IT Certification Program. A developer that pursues such updates to its certified Health IT Module(s) must:

* * * * *

■ 16. Amend § 170.406 by revising paragraphs (a)(4) and (5) to read as follows:

§ 170.406 Attestations.

(a) * * *

(4) Section 170.404 if the health IT developer has a Health IT Module(s) certified to any of the certification criteria adopted in § 170.315(g); and such health IT developer must also ensure that health IT allows for health information to be exchanged, accessed, and used, in the manner described in § 170.404; and

(5) Section 170.405 if a health IT developer has a Health IT Module(s) certified to any one or more ONC Certification Criteria for Health IT set forth in § 170.405(a).

* * * * *

■ 17. Amend § 170.407 by:

■ a. Revising the section heading and paragraphs (a)(1)(ii)(B) and (C) and (a)(3); and

■ b. Revising and republishing paragraph (b).

The revisions and republication read as follows:

§ 170.407 Insights.

(a) * * *

(1) * * *

(ii) * * *

(B) Have health IT certified to the certification criteria specified in each measure in paragraph (a)(3) of this section; or

(C) Have any users using the certified health IT specified in each measure in paragraph (a)(3) of this section for each reporting period.

* * * * *

(3) *Measures—(i) Use of FHIR in apps through certified health IT.* If a health IT developer has a Health IT Module certified to § 170.315(g)(10), then the health IT developer must submit responses on the number of requests made to distinct certified health IT deployments that returned FHIR resources, number of distinct certified health IT deployments active at any time, the number of distinct deployments active at any time that returned FHIR resources in response to API calls from apps connected to certified health IT, including stratifying responses by the following:

(A) User type;

(B) FHIR resource; and

(C) US Core Implementation Guide version.

(ii) *Use of FHIR bulk data access through certified health IT.* If a health IT developer has a Health IT Module certified to § 170.315(g)(10), then the health IT developer must submit

responses for the total number of FHIR bulk data access requests completed through the certified health IT, and the number of distinct deployments of the certified health IT active at any time overall, and by whether at least one bulk data download request was completed.

(b) *Maintenance of Certification.* (1) A health IT developer must provide responses to the Insights Condition of Certification specified in paragraph (a) of this section annually for any Health IT Module that has or has had an active certification as of January 1 for each reporting period under the ONC Health IT Certification Program:

(i) A health IT developer must provide responses for measures specified in:

(A) Paragraphs (a)(3)(i)(A) and (B) of this section beginning July 2027.

(B) Paragraph (a)(3)(i)(C) of this section beginning July 2028.

(C) Paragraph (a)(3)(ii) of this section beginning July 2029.

(ii) [Reserved]

(2) [Reserved]

■ 18. Amend § 170.523 by:

■ a. Revising introductory text of paragraph (f);

■ b. Revising paragraphs (f)(1)(viii) and (xix);

■ c. Removing and reserving paragraphs (f)(1)(xxi) and (p)(1); and

■ d. Revising paragraph (p)(3).

The revisions read as follows.

§ 170.523 Principles of proper conduct for ONC-ACBs.

* * * * *

(f) *Certified product listing.* Provide the Office of the National Coordinator for Health Information Technology (ONC), no less frequently than weekly, a current list of Health IT Modules that have been certified that includes, at a minimum:

(1) * * *

(viii) The certification criterion or criteria to which the Health IT Module has been certified, including the test procedure and test tool version used;

* * * * *

(xix) *Where applicable*, and for each applicable certification criterion, all of the information required to be submitted by Health IT Module developers to meet the safety-enhanced design certification criterion.

* * * * *

(p) * * *

(3) Submit real world testing results by March 15 of each calendar year to ONC for public availability.

* * * * *

■ 19. Amend § 170.550 by:

■ a. Revising paragraph (e);

■ b. Revising and republishing paragraphs (g) and (h)(3); and

■ c. Removing and reserving paragraph (j).

The revisions and republication read as follows:

§ 170.550 Health IT Module certification.

* * * * *

(e) *Standards updates.* ONC–ACBs must provide an option for certification of Health IT Modules consistent with § 170.405(b)(8) or (9) to any one or more of the criteria referenced in § 170.405(a) based on newer versions of standards included in the criteria which have been approved by the National Coordinator for use in certification.

* * * * *

(g) *Health IT Module dependent criteria.* When certifying a Health IT Module to the ONC Certification Criteria for Health IT, an ONC–ACB must certify the Health IT Module in accordance with the certification criteria at:

(1) Section 170.315(g)(3) if the Health IT Module is presented for certification to one or more listed certification criteria in § 170.315(g)(3);

(2) Section 170.315(g)(4);

(3) Section 170.315(g)(5);

(4) Section 170.315(b)(10) when a health IT developer presents a Health IT Module for certification that can store electronic health information at the time of certification by the product, of which the Health IT Module is a part; and

(5) Section 170.315(b)(4) if the Health IT Module is presented for certification to the certification criteria in § 170.315(b)(3).

(h) * * *

(3) *Applicability.* (i) Section 170.315(a)(1) through (3), (5), (14), and (15) are also certified to the certification

criteria specified in § 170.315(d)(1) through (7), (12), and (13).

(ii) Section 170.315(a)(4) and, on and after January 1, 2028, (b)(11), are also certified to the certification criteria specified in § 170.315(d)(1) through (3), (5) through (7), and (12), and, for the time period up to and including December 31, 2027, (d)(13).

(iii) Section 170.315(b)(1) through (3) are also certified to the certification criteria specified in § 170.315(d)(1) through (3), (5) through (8), (12), and (13);

(iv) Section 170.315(c) is also certified to the certification criteria specified in § 170.315(d)(1); (d)(2)(i)(A), (B); (d)(2)(ii) through (v); (d)(3), (5), (12), and (13);

(v) Section 170.315(e)(1) is also certified to the certification criteria specified in § 170.315(d)(1) through (3), (5), (7), (9), (12), and (13);

(vi) [Reserved]

(vii) Section 170.315(f) is also certified to the certification criteria specified in § 170.315(d)(1) through (3), (7), (12), and (13); and

(viii) Section 170.315(g)(10) is also certified to the certification criteria specified in § 170.315(d)(1), (9), (12), and (13); and (d)(2)(i)(A) and (B); (d)(2)(ii) through (v); or (d)(10).

(ix) [Reserved]

* * * * *

■ 20. Amend § 170.555 by revising and republishing paragraph (b)(2) to read as follows:

§ 170.555 Certification to newer versions of certain standards.

* * * * *

(b) * * *

(2) A certified Health IT Module may be upgraded to comply with newer

versions of standards identified as minimum standards in subpart B of this part without adversely affecting its certification status, unless the Secretary prohibits the use of a newer version for certification.

■ 21. Amend § 170.570 by revising the section heading to read as follows:

§ 170.570 Effect of revocation on the certifications issued to Health IT Module(s).

* * * * *

PART 172—TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT

■ 22. The authority citation for part 172 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 5 U.S.C. 552.

■ 23. In part 172, remove the text “ASTP/ONC” and “ASTP/ONC’s” wherever it appears and add, in its place, the text “ONC” and “ONC’s”, respectively.

§ 172.102 [Amended]

■ 24. Amend § 172.102 in the definition of “Applicant QHIN” by removing the text “Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology” and adding in its place “Office of the National Coordinator for Health Information Technology”.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–21943 Filed 10–26–26; 11:15 am]

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Part III

The President

Proclamation 11074—Adjusting Imports of Wind Turbines and Their Parts and Components Into the United States

Proclamation 11075—National Seafood Month, 2026

Executive Order 14438—Decreasing Housing Costs for the American People

Presidential Determination No. 2027–01 of October 22, 2026—Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended, on Domestic Petroleum Production, Refining, and Logistics Capacity

Presidential Documents

Title 3—

Proclamation 11074 of October 22, 2026

The President

Adjusting Imports of Wind Turbines and Their Parts and Components Into the United States

By the President of the United States of America

A Proclamation

1. Within the past 90 days, the Secretary of Commerce (Secretary) transmitted to me a report on his investigation into the effects of imports of wind turbines and their parts and components on the national security of the United States under section 232 of the Trade Expansion Act of 1962, as amended, 19 U.S.C. 1862 (section 232). Based on the facts considered in that investigation, and taking into account the close relation of the economic welfare of the Nation to our national security and other relevant factors, *see* section 232(d) (19 U.S.C. 1862(d)), the Secretary found and advised me of his opinion that wind turbines and their components and subcomponents are being imported into the United States under such circumstances as to threaten to impair the national security of the United States and provided me recommendations for action under section 232 to adjust the imports of wind turbines and their components and subcomponents so that such imports will not threaten to impair the national security of the United States.

2. Among other things, the Secretary found that wind energy is an unreliable and intermittent energy source and that the use of wind energy diverts the United States electrical grid from more reliable energy sources. The Secretary also found that products used to generate and use wind energy pose serious national security concerns, including by relying on foreign parts that contain cybersecurity vulnerabilities that could lead to remote control access to wind turbines and cause power disruption; undermining the United States' electrical grid, and potentially causing disruptions to critical infrastructure; interfering with national airspace and air safety; and causing radar interference that can affect air traffic control, weather forecasting, homeland security, and national defense missions. And the Secretary found that imports of wind turbine components and subcomponents have increased over the last decade, and that United States wind energy is reliant on imports of foreign produced wind turbine components and subcomponents.

3. The Secretary found that wind energy is intermittent and burdensome on the United States electrical grid. Wind energy is inherently intermittent, and this unpredictability undermines wind's suitability as a standalone energy source compared to the steady output of fossil fuel or nuclear energy, particularly if used for critical infrastructure. And even though wind energy comprises only a small portion of total utility scale power generated in the United States, grid operators must frequently rely upon fast-ramping fossil fuel backup generators to compensate for wind energy's high net load variability and maintain grid stability. This results in higher operational costs and increased maintenance burdens.

4. The Secretary found that the unpredictability of wind energy makes it less reliable than other energy sources that conversely provide steady output as standalone energy sources. Given wind energy's intermittent reliability, use of wind energy diverts the United States electrical grid from more reliable energy sources. And resources that are used to support wind

energy and wind energy projects could instead have been used to strengthen more reliable energy sources that are essential to the national and economic security of the United States.

5. The Secretary found that the use of wind energy poses unique national security risks compared to other energy sources. Among other things, wind energy products have serious cybersecurity vulnerabilities that can cause power disruption; interfere with radar, thus significantly affecting air traffic control, weather forecasting, homeland security, and national defense missions; and burden the United States electrical grid, including by diverting the United States electrical grid from more reliable energy sources.

6. More specifically, the Secretary found that wind energy products—particularly foreign imported products—present unique cybersecurity risks that could lead to remote control access to wind turbines and cause power disruption. Inverters are a crucial piece of electrical equipment for using wind energy, as inverters convert the electrical energy generated by wind turbines into a form of energy that can be used by the power grid or local systems. The vast majority of these inverters are produced outside the United States and imported into the United States. But modern networked inverters used in wind farms—particularly those produced and imported from outside the United States—are an exploitable vulnerability that can allow remote access and interference with United States power systems. Attackers could gain remote control over power generation, which presents risks of power disruption or sabotage of installation facilities.

7. The Secretary found that wind turbines can affect ground and air-based radars by creating “clutter,” reducing detection sensitivity, obscuring potential targets, and scattering radio wave returns. For example, clutter from wind projects obscures legitimate moving targets and generates false targets in the vicinity of the wind projects, and some mitigation techniques can lead to missing actual targets. These circumstances thus pose grave national security risks to the United States, particularly in response to threats (e.g., unauthorized aircraft) targeting sensitive United States critical infrastructure. And degraded radar performance from wind turbines can also have negative implications on weather forecasting, air traffic management, and military radar systems.

8. The Secretary found that the United States is reliant on imports of foreign produced wind turbine components and subcomponents and that imports of wind turbine components and subcomponents have increased over the last decade, while domestic manufacturing capacity for certain products, such as blades, has not meaningfully increased.

9. In light of these findings and the other findings in the Secretary’s report, the Secretary recommended a range of actions to adjust the imports of wind turbines and their components and subcomponents so that such imports will not threaten to impair the national security.

10. Moreover, in Proclamation 9704 of March 8, 2018 (Adjusting Imports of Aluminum Into the United States), Proclamation 9705 of March 8, 2018 (Adjusting Imports of Steel Into the United States), and Proclamation 10962 of July 30, 2025 (Adjusting Imports of Copper Into the United States), I found that aluminum, steel, and copper are being imported into the United States in such quantities and under such circumstances as to threaten to impair the national security of the United States and took action under section 232 to address the national security threats found in those proclamations. Certain wind turbine components and subcomponents are made of significant amounts of aluminum, steel, or copper and contribute to the national security threat found in Proclamation 9704, Proclamation 9705, and Proclamation 10962. Accordingly, certain wind turbine components and subcomponents are subject to the tariffs imposed in Proclamation 9704, as amended; Proclamation 9705, as amended; or Proclamation 10962, as amended, to address the national security threats found in those proclamations.

11. After considering the Secretary's report, the factors in section 232(d) (19 U.S.C. 1862(d)), and other relevant factors and information, I concur with the Secretary's finding that wind turbines and their components and subcomponents are being imported into the United States under such circumstances as to threaten to impair the national security of the United States.

12. In my judgment, and in light of the Secretary's report, the factors in section 232(d) (19 U.S.C. 1862(d)), and other relevant factors and information, I determine that it is necessary and appropriate to enter into negotiations with foreign trading partners to adjust the imports of wind turbines and their components and subcomponents to address the national security threat found in this proclamation.

13. I therefore direct the Secretary and the United States Trade Representative (Trade Representative) to jointly pursue negotiation of agreements or continue any current negotiations of agreements to address the threatened impairment of the national security with respect to imported wind turbines and their components and subcomponents, with any foreign trading partner the Secretary and the Trade Representative deem appropriate, and to update me on the progress of such negotiations within 180 days of the date of this proclamation. Under current circumstances, this plan of action is necessary and appropriate to address the threatened impairment of the national security found in this proclamation. Depending on the status or outcome of such negotiations, I may consider alternative remedies in the future.

14. Section 232 authorizes the President to take action to adjust the imports of an article and its derivatives that are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security of the United States. Section 232 includes the authority to adopt and carry out a plan of action, with adjustments over time, to address the national security threat. That initial plan of action may include negotiations of agreements along with other actions to adjust imports to address the national security threat, including tariffs. Moreover, if action under section 232 includes the negotiation of an agreement, such as one contemplated in section 232(c)(3)(A)(i) (19 U.S.C. 1862(c)(3)(A)(i)), the President may also take other actions he deems necessary to adjust imports so that such imports will not threaten to impair the national security of the United States, including if such an agreement is not entered into within 180 days of the date of this proclamation or is not being carried out or is ineffective. *See* 19 U.S.C. 1862(c)(3)(A).

15. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483) (section 604), authorizes the President to embody in the Harmonized Tariff Schedule of the United States the substance of statutes affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, including section 232; section 604; and section 301 of title 3, United States Code, do hereby proclaim as follows:

(1) The Secretary and the Trade Representative, and any senior executive branch official they deem appropriate, shall jointly pursue or continue pursuing negotiations of agreements to address the national security threat found in this proclamation.

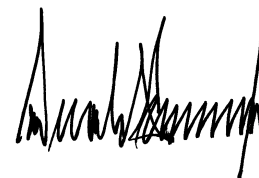
(2) The Secretary and the Trade Representative, in consultation with any other senior executive branch officials they deem appropriate, shall, from time to time, update me on the status or outcome of the negotiations described in this proclamation. The Secretary and the Trade Representative shall provide at least one of these updates within 180 days of the date of this proclamation.

(3) The Secretary shall continue to monitor imports of wind turbines and their components and subcomponents. The Secretary also shall, from

time to time, in consultation with any senior executive branch officials the Secretary deems appropriate, review the status of such imports with respect to the national security. The Secretary shall inform me of any circumstances that, in the Secretary's opinion, might indicate the need for further action by the President under section 232.

(4) Nothing in this proclamation modifies the tariffs imposed pursuant to Proclamation 9704, as amended; Proclamation 9705, as amended; and Proclamation 10962, as amended, or any other tariffs imposed pursuant to section 232.

(5) Any provision of previous proclamations and Executive Orders that is inconsistent with this proclamation is superseded to the extent of such inconsistency. If any provision of this proclamation or the application of any provision of this proclamation to any individual or circumstance is held to be invalid, the remainder of this proclamation and the application of its provisions to any other individual or circumstance shall not be affected. IN WITNESS WHEREOF, I have hereunto set my hand this twenty-second day of October, in the year of our Lord two thousand twenty-six, and of the Independence of the United States of America the two hundred and fifty-first.



Presidential Documents

Proclamation 11075 of October 22, 2026

National Seafood Month, 2026

By the President of the United States of America

A Proclamation

Across our Nation's harbors and fishing communities, the unrivaled skill and resolve of American fishermen and seafood producers turn the bounty of our waters into food for our families and enduring economic strength. Food security is national security—we recognize that our fisheries are a vital pillar of American independence. This National Seafood Month, I join the American people in celebrating these hardworking men and women and reaffirm my commitment to helping them compete, prosper, and lead the world in seafood production.

From the fishing ports of early America to today's seafood farms and processing plants, this great industry has rewarded enterprise, sustained family businesses, and helped forge the unmatched spirit of determination that defines our maritime workforce. For generations, our fishermen have braved rough seas and punishing storms, spending long days far from home to earn an honest living and provide for the people they love. Across our land, the incredible American seafood industry harvests nearly 8.5 billion pounds of world-class food annually, sustains more than a million jobs, and fuels more than \$173 billion in commerce, bringing wealth and opportunity to communities across our great Nation. And now, as we usher in a new Golden Age of seafood production, we are ensuring our fishing communities remain places where the next generation can raise a family, build a business, and pursue their own share of the American Dream.

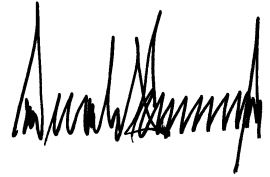
Since returning to office, I have taken decisive action to restore American seafood competitiveness and give our fishing communities greater freedom to grow and succeed. Last year, I signed an Executive Order to restore American seafood competitiveness, and my Administration recently launched the Department of Agriculture Office of Seafood. I have also signed three proclamations to restore commercial fishing access to nearly 5,000 square miles in the Atlantic Ocean and to hundreds of thousands of square miles in the Pacific, enabling American vessels to work additional fishing grounds and compete more effectively in the global seafood market. Under my leadership, we delivered the largest single-year quota increase in the history of the United States Atlantic bluefin tuna fishery, secured a massive 1,200 percent quota increase for Atlantic mackerel, and revived the West Coast salmon season to yield the first full commercial fishery in 3 years. My Administration was also proud to allocate \$123.6 million in fishery disaster assistance to help communities recover from devastating losses, strengthen shoreside infrastructure, and support job retraining to help workers get back on their feet. We will continue slashing burdensome regulations so our fishermen can reinvest in their fleets, expand their operations, and keep more of what they earn. Through these historic efforts, we are putting American fishermen first and fighting to make our Nation the strongest, most successful seafood producer in the world.

As our Nation celebrates National Seafood Month, we give thanks to the families whose skill and sacrifice have built and sustained this essential American industry for over 250 years. We will stand with them as we build a future of thriving ports, successful businesses, and an American

seafood industry that is stronger, more competitive, and more prosperous than ever before.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim October 2026 as National Seafood Month. I call upon all Americans to express their thanks for the American citizens who sustain this crucial industry, and to mark this month with appropriate events and ceremonies.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-second day of October, in the year of our Lord two thousand twenty-six, and of the Independence of the United States of America the two hundred and fifty-first.

A handwritten signature in black ink, appearing to be "Donald J. Trump", written in a stylized, cursive script.

Presidential Documents

Executive Order 14438 of October 22, 2026

Decreasing Housing Costs for the American People

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. The American Dream of homeownership is a vital pillar of our great country. It is the policy of my Administration to reduce regulatory barriers to mortgage origination and costs impeding homeownership; embrace innovative risk and value assessment technologies that incorporate Super Intelligence to drive down mortgage and homeownership costs; and promote competition and innovation throughout the housing and mortgage market.

Sec. 2. Proactive Cancellation of Excessive Mortgage Insurance. (a) The Director of the Federal Housing Finance Agency (Director) shall, if he determines that it is in the best interests of the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation (Enterprises) or the Federal Housing Finance Agency (FHFA), and the American public, direct the Enterprises to establish a pilot program, applicable only to mortgages made after the establishment of the pilot program, that periodically reviews single-family mortgage loans they own, guarantee, or securitize, using automated valuation models and other available data to assess current market value, and to identify borrowers who appear to satisfy equity and other requirements for cancellation of mortgage insurance.

(b) The Director shall direct the Enterprises to establish procedures for the pilot program, including financial safety and soundness standards and payment-history requirements, under which mortgage insurance is canceled proactively when an Enterprise determines that:

- (i) the borrower satisfies applicable equity requirements based on the property's current market value, as determined through an automated valuation model or other means approved by the Director;
- (ii) cancellation is consistent with financial safety and soundness and with the Enterprise's contractual obligations; and
- (iii) the borrower satisfies all other applicable statutory, contractual, regulatory, and Enterprise requirements for cancellation.

(c) The Director shall direct the Enterprises to require servicers, to the extent permitted by law and operationally feasible, to notify borrowers promptly when mortgage insurance may be canceled under the pilot program, and to reduce or eliminate unnecessary documentation requests, appraisal costs, and other administrative barriers to cancellation.

Sec. 3. Standardizing the Permitting of Homes. (a) To increase the quality and lower the cost of building a home, there is hereby established the Task Force on Manufactured Housing Innovation (Task Force), which shall be co-chaired by the Secretary of Housing and Urban Development and the Director of the Federal Housing Finance Agency, or their designees, and shall include the Secretary of Agriculture, the Secretary of Commerce, and the Secretary of Veterans Affairs, or their designees. The co-chairs may invite the heads of other executive departments and agencies (agencies) to participate, as appropriate.

(b) Within 180 days of the date of this order, the Task Force shall submit to the President, through the Assistant to the President for Economic Policy, recommendations to facilitate the use of modern manufacturing methods in the production of manufactured and other factory-built housing eligible for Federal housing programs, including actions to:

(i) promote specifications, certifications, inspections, and approvals across Federal housing and housing-finance programs;

(ii) establish reciprocal recognition among agencies of licenses, certifications, approvals, and inspections, where doing so would avoid unnecessary duplication;

(iii) eliminate Federal requirements and duplicative reviews that unnecessarily impede automation, modularization, standardized production, or other advanced manufacturing techniques, or that increase the time or cost of bringing homes to market;

(iv) use Federal financing, insurance, guarantee, purchasing, and other program authorities to encourage innovation and increased production of affordable manufactured and factory-built homes; and

(v) promote competition among manufacturers and other market participants while maintaining appropriate standards for safety, quality, durability, and consumer protection.

(c) The Task Force shall also evaluate whether, and under what existing statutory authorities, Federal grant funding may be conditioned on, or be used to incentivize, State and local adoption of standardized permitting and licensing for manufactured and other factory-built housing, consistent with the best practices issued under section 4(a) of Executive Order 14394 of March 13, 2026 (Removing Regulatory Barriers to Affordable Home Construction), and shall prepare legislative recommendations to codify the policies set forth in this subsection.

(d) The heads of the agencies represented on the Task Force shall, within their respective authorities, take appropriate action to implement the Task Force's recommendations.

Sec. 4. *Reducing Excessive Title Insurance, Especially in the Refinancing of Americans Homes.* (a) The Director shall, if he determines that it is in the best interests of the Enterprises or the FHFA, and the American public, and consistent with financial safety and soundness, the Director's authorities as regulator and conservator, and applicable law, direct the Enterprises to expand the title acceptance pilot into an ongoing program, available nationwide through both Enterprises, under which an Enterprise may accept an automated title review or other title-risk assessment approved by the FHFA in lieu of a lender's title insurance policy on eligible refinance transactions.

(b) In expanding the program, the Director shall consider:

(i) extending eligibility to refinance transactions with loan-to-value ratios above the current 80 percent limit where title risk remains low;

(ii) removing geographic limitations and certifying additional title-assessment providers to promote competition;

(iii) waiving appraisals, income re-verification, and other documentation requirements for limited cash-out refinances that reduce the borrower's monthly payment, where the Enterprise's existing data support doing so; and

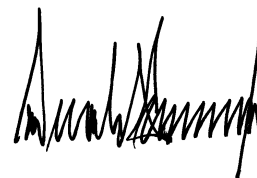
(iv) reducing or eliminating loan-level price adjustments and other Enterprise fees on such refinances.

(c) The Director shall require that cost savings resulting from the program be passed through to borrowers and that lenders inform borrowers of those savings.

Sec. 5. *Department of Agriculture and Department of Veterans Affairs Direct Loan Rates.* The Secretary of Agriculture and the Secretary of Veterans Affairs shall, consistent with applicable law, including 42 U.S.C. 1490a(a)(1)(B) and 38 U.S.C. 3762(c)(1), and available appropriations, reduce the interest rates charged on single-family home loans made directly by their respective departments.

Sec. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
 - (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.
- (d) The costs for publication of this order shall be borne by the Federal Housing Finance Agency.

A handwritten signature in black ink, appearing to be a stylized name with a long, sweeping horizontal stroke at the end.

THE WHITE HOUSE,
October 22, 2026.

Presidential Documents

Presidential Determination No. 2027–01 of October 22, 2026

Presidential Determination Pursuant to Section 303 of the Defense Production Act of 1950, as Amended, on Domestic Petroleum Production, Refining, and Logistics Capacity

Memorandum for the Secretary of War

On January 20, 2025, I issued Executive Order 14156 (Declaring a National Energy Emergency), under the National Emergencies Act. That order found that America's inadequate energy production, transportation, refining, and generation capacity constitute an unusual and extraordinary threat to the Nation's economy, national security, and foreign policy. It emphasized that our Nation's current inadequate and intermittent energy supply leaves us vulnerable to hostile foreign actors and poses an imminent and growing threat to the prosperity and national security of the United States.

Consistent with that declaration, I find that ensuring resilient domestic petroleum production, refining, and logistics capacity is central to United States defense readiness. Petroleum fuels the Nation's Armed Forces, industrial base, and crucial infrastructure. Without immediate Federal action, United States defense capabilities will remain vulnerable to disruption.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, including section 303 of the Defense Production Act of 1950, as amended (the "Act") (50 U.S.C. 4533), I hereby determine, pursuant to section 303(a)(5) of the Act, that:

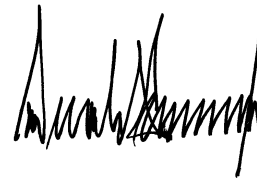
(1) domestic petroleum production, refining, and logistics capacity, including exploration and production, gathering and transmission pipelines, storage, and marine terminals, are industrial resources, materials, or critical technology items essential to the national defense;

(2) without Presidential action under section 303 of the Act, United States industry cannot reasonably be expected to provide these capabilities for the needed industrial resource, material, or critical technology item in a timely manner due to constrained financing, long lead times, permitting and infrastructure bottlenecks, and supply chain limitations; and

(3) purchases, purchase commitments, financial support for the development of production capabilities, or other action pursuant to section 303 of the Act are the most cost-effective, expedient, and practical alternative methods for meeting this need.

I have declared a national emergency under Executive Order 14156, and I further determine that action to expand the domestic petroleum production, refining, and logistics capacity is necessary to avert an industrial resource or critical technology item shortfall that would severely impair national defense capability. Therefore, pursuant to section 303(a)(7) of the Act, I waive the requirements of section 303(a)(1)–(a)(6) of the Act for the purpose of expanding such capability.

You are authorized and directed to implement this determination, including making necessary purchases, commitments, and financial instruments to enable these projects, and to publish this determination in the *Federal Register*. Any provision of previous memoranda, proclamations, and Executive Orders that is inconsistent with this determination is superseded to the extent of such inconsistency.

A handwritten signature in black ink, appearing to be a stylized name, possibly "Donald Trump", written in a cursive, somewhat jagged style.

THE WHITE HOUSE,
Washington, October 22, 2026

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