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FEDERAL REGISTER

Vol. 89 Friday,

No. 23 February 2, 2024

Pages 7267–7598

OFFICE OF THE FEDERAL REGISTER

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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.

POSTAL SERVICE

5 CFR Part 7001

Supplemental Standards of Ethical Conduct for Employees of the United States Postal Service; Correction

AGENCY: Postal Service™.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to a final rule that was published in the **Federal Register** on August 8, 2023. The final rule amended the United States Postal Service's (Postal Service) Supplemental Standards of Ethical Conduct for Employees of the United States Postal Service (Supplemental Standards), which were issued by the Postal Service with the concurrence of the United States Office of Government Ethics (OGE).

DATES: *Effective date:* February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Ruth Stevenson, Chief Counsel, Ethics & Legal Compliance, United States Postal Service, 475 L'Enfant Plaza SW, Washington, DC 20260–1101, 202–268–6936.

SUPPLEMENTARY INFORMATION:

I. Background

On August 8, 2023, the Postal Service published a final rule amending its Supplemental Standards. 88 FR 53351. The final rule updated the outside employment and activity provisions (including prior approval requirements and prohibitions), added new requirements applicable to Postal Service Office of Inspector General (OIG) employees, Postal Service Governors, the Postmaster General, and the Deputy Postmaster General, and made limited technical and ministerial changes.

II. Need for Correction

The final rule incorrectly listed two internal cross-reference citations contained in the outside employment and business activities restrictions section, § 7001.102. This technical correction amends the Supplemental Standards by updating the cross-references.

List of Subjects in 5 CFR Part 7001

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

For the reasons set forth in the preamble, the United States Postal Service, with the concurrence of the United States Office of Government Ethics, amends 5 CFR part 7001 as follows:

PART 7001—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE UNITED STATES POSTAL SERVICE

■ 1. The authority citation for 5 CFR part 7001 is revised to read as follows:

Authority: 5 U.S.C. 7301; 5 U.S.C. Chapter 131; 39 U.S.C. 401; 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 CFR 2635.105, 2635.802, and 2635.803.

■ 2. In § 7001.102, example 1 to paragraph (a)(2)(ii) and paragraph (c)(2) are revised to read as follows:

§ 7001.102 Restrictions on outside employment and business activities.

(a) * * *

(2) * * *

(ii) * * *

Example 1 to paragraph (a)(2)(ii): United Parcel Service (UPS), Federal Express (FedEx), Amazon, or DHL offers a part-time job to a Postal Service employee. Because UPS, FedEx, Amazon and DHL are persons engaged in the delivery outside the mails of mailable matter (as defined in paragraph (d)(3) of this section) that is not daily newspapers, the employee may not engage in employment with UPS, FedEx, Amazon, or DHL in any location in any capacity while continuing employment with the Postal Service in any location in any capacity. If the employee chooses to work for UPS, FedEx, Amazon, or DHL, the employee must end his or her postal employment before commencing work for that company.

* * * * *

(c) * * *

(2) *When prior approval required.* A Special Agent or Criminal Investigator shall also request and obtain written approval prior to engaging in outside employment or business activities which he or she is required to report under paragraph (c)(1) of this section. A request for approval shall be submitted to the OIG's Office of General Counsel, which will be reviewed under the same standard stated in paragraph (b)(4) of this section.

* * * * *

Ruth Stevenson,

Chief Counsel, Ethics and Legal Compliance United States Postal Service.

Shelley Finlayson,

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

[FR Doc. 2024–01866 Filed 2–1–24; 8:45 am]

BILLING CODE 7710–12–P

FEDERAL TRADE COMMISSION

16 CFR Part 305

RIN 3084–AB15

Energy Labeling Rule

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''Commission'') amends its Energy Labeling Rule (''Rule'') by publishing new ranges of comparability for required EnergyGuide labels on televisions.

DATES: The amendments are effective May 2, 2024.

ADDRESSES: Relevant portions of the record of this proceeding, including this document, are available at *https://www.ftc.gov.*

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, (202) 326–2889, or Hong Park, (202) 326–2158, Attorneys, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Room CC–6316, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

The Commission issued the Energy Labeling Rule in 1979 pursuant to the Energy Policy and Conservation Act of

1975 (''EPCA'').[1] The Rule covers several categories of major household products, including televisions. It requires manufacturers of covered products to disclose specific energy consumption or efficiency information (derived from Department of Energy (''DOE'') test procedures) at the point of sale. In addition, each label must include a ''range of comparability'' indicating the highest and lowest energy consumption or efficiencies for comparable models. The Commission updates these ranges periodically.

II. Range Updates for Televisions

The Commission amends its television ranges in 16 CFR 305.25(f)(5) based on test data generated from DOE's revised test procedure. In a rule document published in October 2022 issuing range updates for other covered products, the Commission postponed television range updates until DOE finalized a new test procedure for those products.[2] The document stated the FTC would publish updated ranges after data derived from the upcoming test procedure became available. DOE has issued a final test update, and new data is now available.[3] Accordingly, this publication contains the updates to the television ranges, along with related sample labels. In addition, these amendments update the cost figure on the television label to 16 cents per kWh based on the most recent national electricity cost information published by DOE.[4] Manufacturers should begin using the new ranges on labels for newly-produced units no later than May 2, 2024.

III. Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to a Regulatory Flexibility Act analysis [5] are not applicable to this proceeding because the amendments do not impose any new obligations on entities regulated by the Energy Labeling Rule. These technical amendments merely provide a routine change to the range and cost information already required on EnergyGuide labels. The Commission has concluded, therefore, that a regulatory flexibility analysis is not necessary, and certifies, under Section 605 of the Regulatory Flexibility Act, that the amendments announced today will not have a significant economic impact on a substantial number of small entities.[6]

IV. Paperwork Reduction Act

The current Rule contains recordkeeping, disclosure, testing, and reporting requirements that constitute information collection requirements as defined by 5 CFR 1320.3(c), the definitional provision within the Office of Management and Budget (''OMB'') regulations that implement the Paperwork Reduction Act (''PRA''). OMB has approved the Rule's existing information collection requirements through February 29, 2024 (OMB Control No. 3084–0069). The amendments now being adopted do not change the substance or frequency of the recordkeeping, disclosure, or reporting requirements and, therefore, do not require further OMB clearance.

V. Other Matters

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

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR part 305 is amended as follows:

PART 305—ENERGY AND WATER USE LABELING FOR CONSUMER PRODUCTS UNDER THE ENERGY POLICY AND CONSERVATION ACT (''ENERGY LABELING RULE'')

■ 1. The authority citation for Part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

■ 2. In § 305.25, revise paragraphs (f)(4) and (5) to read as follows:

§ 305.25 Television labeling.

* * * * *

(f) * * *

(4) Estimated annual energy costs determined in accordance with this part, and based on a usage rate of 5 hours in on mode and 19 hours in standby (sleep) mode per day, and an electricity cost rate of 16 cents per kWh.

(5) The applicable ranges of comparability for estimated annual energy costs based on the labeled product's diagonal screen size, according to the following table:

TABLE 1 TO PARAGRAPH (f)(5)

Screen size (diagonal)	Annual energy cost ranges for televisions	
	Low	High
16–20″ (16.0 to 20.49″)	$7	$7
21–23″ (20.5 to 23.49″)	(*)	(*)
24–29″ (23.5 to 29.49″)	5	15
30–34″ (29.5 to 34.49″)	8	30
35–39″ (34.5 to 39.49″)	19	20
40–44″ (39.5 to 44.49″)	13	51
45–49″ (44.5 to 49.49″)	40	40
50–54″ (49.5 to 54.49″)	22	51
55–59″ (54.5 to 59.49″)	24	69
60–64″ (59.5 to 64.49″)	29	113
65–69″ (64.5 to 69.49″)	27	110
69.5″ or greater	32	155

* No data.

[1] 42 U.S.C. 6294; 44 FR 66466 (Nov. 19, 1979). EPCA also requires the Department of Energy (''DOE'') to set minimum efficiency standards and develop test procedures to measure energy use.

[2] 87 FR 61465 (Oct. 12, 2022); *see* 87 FR 11892 (Mar. 2, 2022) (DOE NPRM).

[3] 88 FR 16082 (Mar. 15, 2023) (DOE Final Rule).

[4] 88 FR 58575 (Aug. 28, 2023) (cost figure rounded consistent with 16 CFR 305, Appendices K1 and K2).

[5] *See* 5 U.S.C. 603–604.

[6] 5 U.S.C. 605.

* * * * *

■ 3. In § 305.27, revise paragraph (b)(1)(i)(F) to read as follows:

§ 305.27 Paper catalogs and websites.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(F) *Televisions.* The estimated annual operating cost determined in accordance with this part, and a disclosure stating ''Your energy cost depends on your utility rates and use. The estimated cost is based on 16 cents per kWh and 5 hours of use per day. For more information, visit *www.ftc.gov/energy.*''

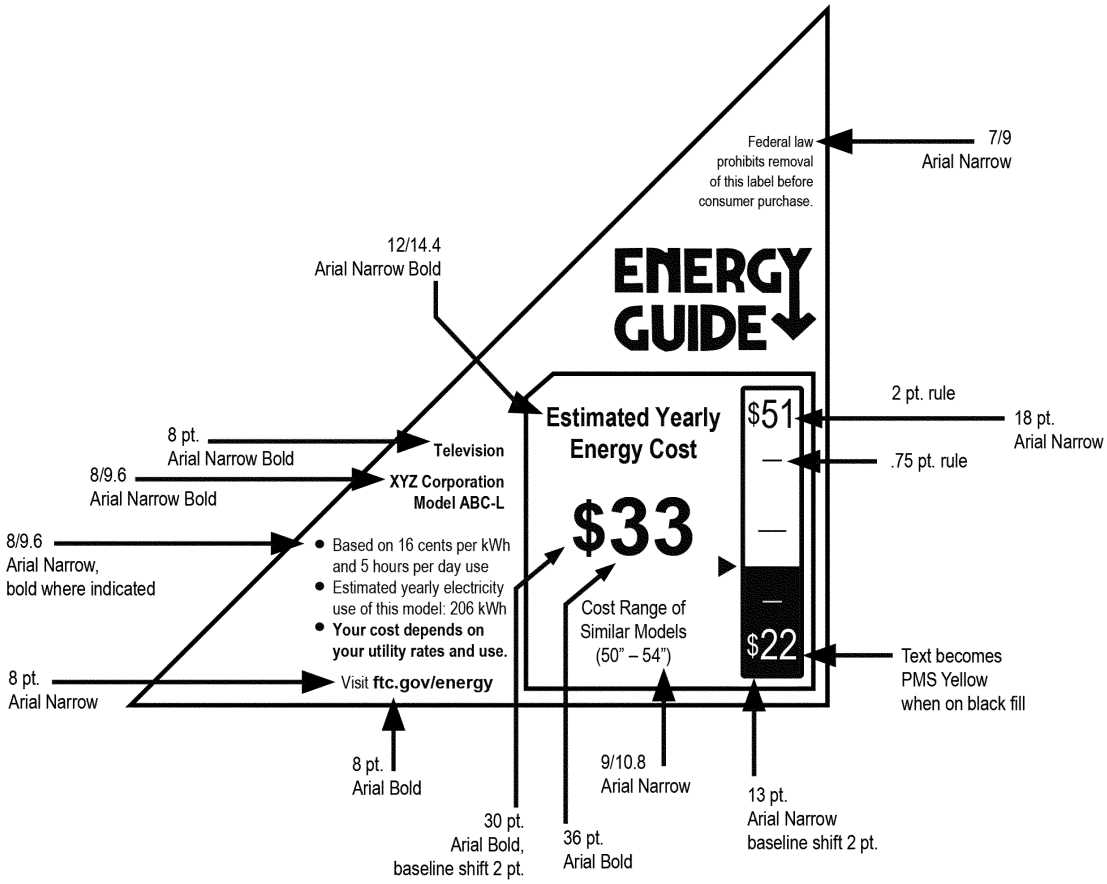
* * * * *

■ 4. Revise Prototype Labels 8, 9, and 10 and Sample Labels 14, 15, and 16 in Appendix L to read as follows:

BILLING CODE 6750–01–P

Appendix L to Part 305—Sample Labels

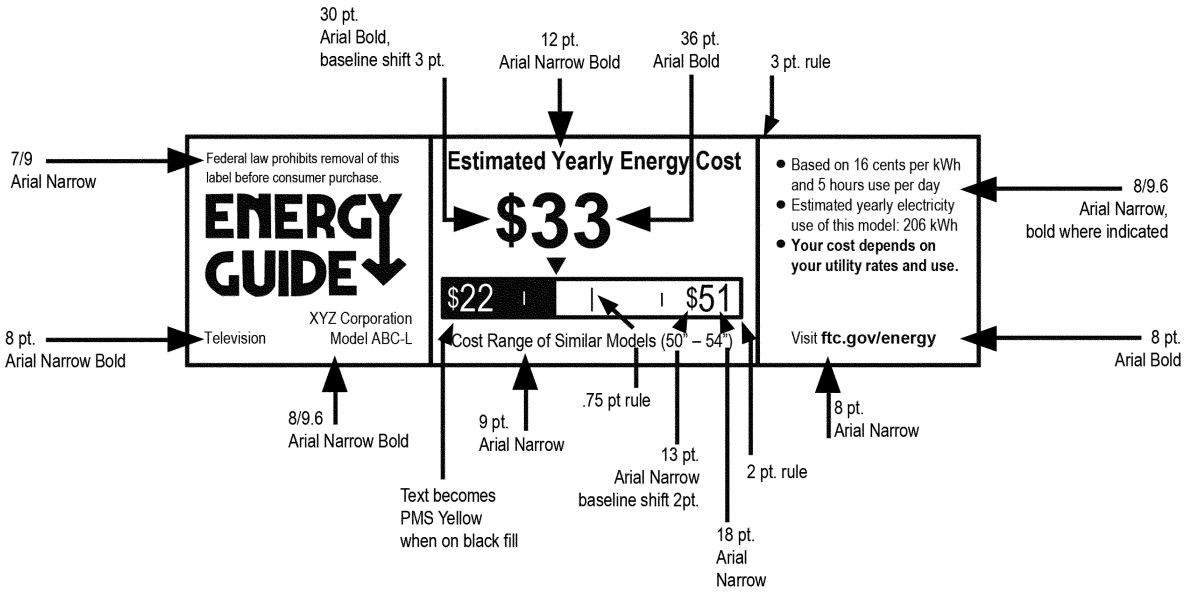
* * * * *



Minimum label size right angle triangle 4.5" x 4.5"

* Typeface is Arial Narrow and Arial or equivalent type style. Type sizes shown are minumum allowable. Use bold or heavy typeface where indicated. Type is black printed on process yellow or equivalent color background. Energy Star logo, if applicable, must be at least 0.36" wide.

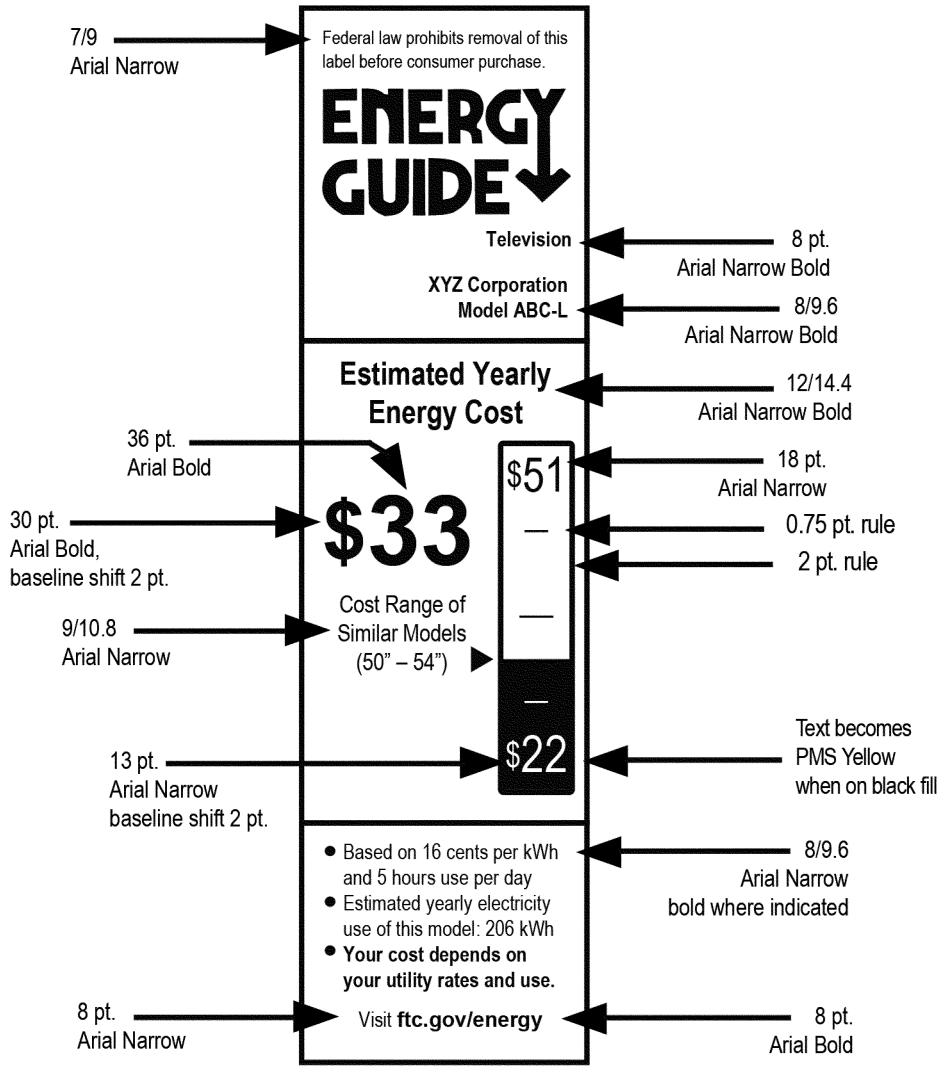
Prototype Label 8, Triangular Television Label



Minimum label size 1.5" x 5.25

* Typeface is Arial Narrow and Arial or equivalent type style. Type sizes shown are minumum allowable. Use bold or heavy typeface where indicated. Type is black printed on process yellow or equivalent color background. Energy Star logo, if applicable, must be at least 0.36" wide.

Prototype Label 9, Horizontal Rectangular Television Label

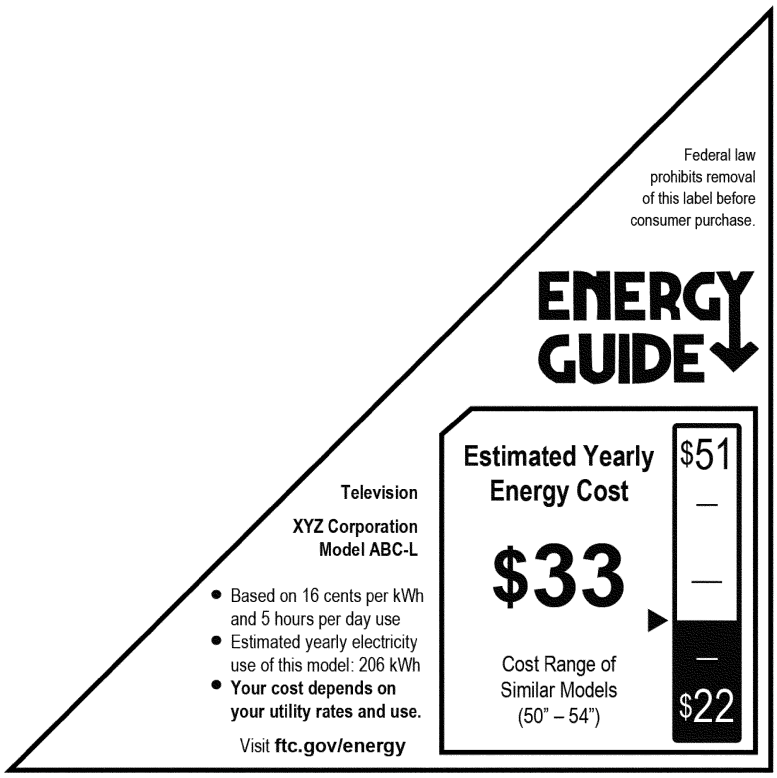


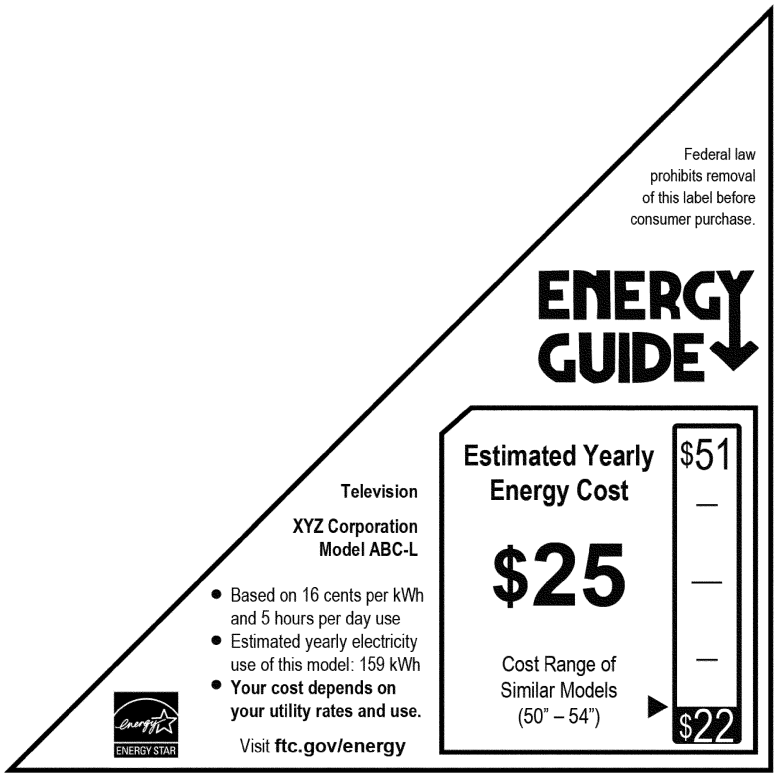
Minimum label size 1.5" x 5.5"

* Typeface is Arial Narrow and Arial or equivalent type style. Type sizes shown are minumum allowable. Use bold or heavy typeface where indicated. Type is black printed on process yellow or equivalent color background. Energy Star logo, if applicable, must be at least 0.36" wide.

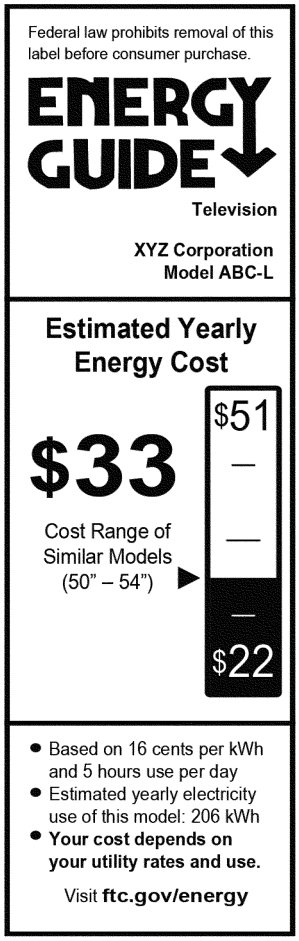
Prototype Label 10, Vertical Rectangular Television Label

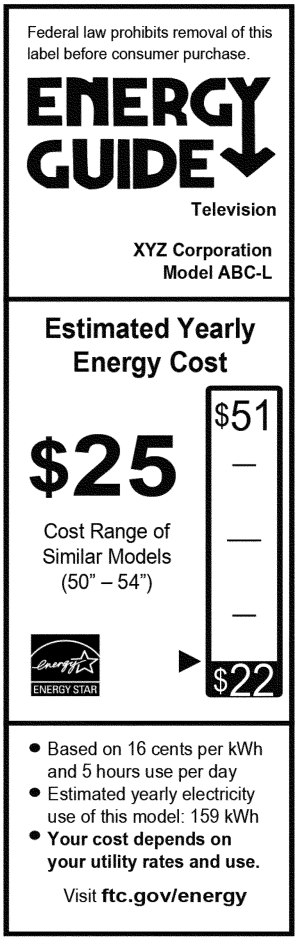
* * * * *



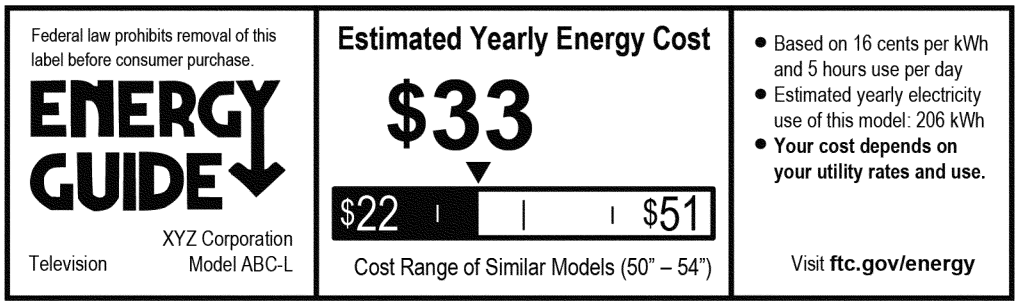


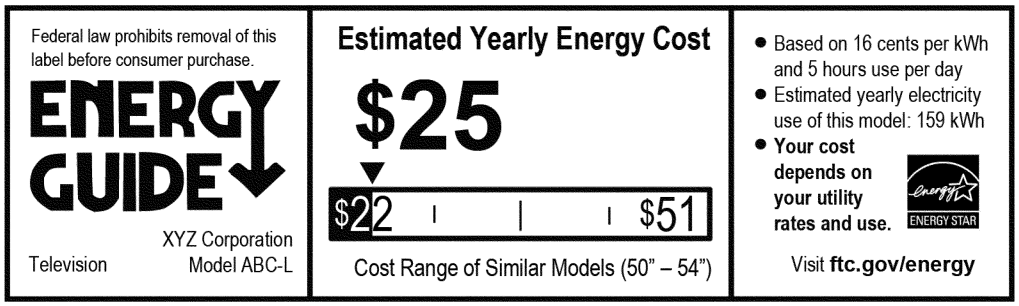
Sample Label 14, Triangular Television Labels





Sample Label 15, Vertical Television Labels





Sample Label 16, Horizontal Television Labels

* * * * *

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2024–02036 Filed 2–1–24; 8:45 am]

BILLING CODE 6750–01–C

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 202

[Docket No. FR–6321–F–02]

RIN 2502–AJ63

Changes in Branch Office Registration Requirements

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: The Office of the Assistant Secretary for Housing—Federal Housing Commissioner is issuing final regulations to amend the Department of Housing and Urban Development's (HUD) requirement for branch office registration. The final rule removes the requirement that lenders and mortgagees register each branch office where they conduct FHA business with HUD. After considering public comments received in response to the proposed rule HUD published on March 1, 2023, this final rule adopts the proposed rule without change.

DATES: Effective March 4, 2024.

FOR FURTHER INFORMATION CONTACT: Timothy Laramie, Mortgagee Approval Analyst, U.S. Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, telephone number 202–402–6814 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 1, 2023, HUD published the ''Changes in Branch Office Registration Requirements'' proposed rule (''the proposed rule'') in the **Federal Register.** [1] In the proposed rule, HUD sought to revise 24 CFR 202.5(k) and (i) by eliminating the requirement that a lender or mortgagee register all branch offices used to conduct FHA business. This change would give lenders and mortgagees (1) the option to select which offices to register and maintain as branch offices with HUD, and (2) make fees applicable to each branch office that a lender or mortgagee registers with HUD, rather than applying fees to each branch office where they are authorized to originate Title I or Title II loans. HUD based these changes on the mortgage industry's evolution over time, the advancement of technology, and due to no longer needing to maintain several branch offices to conduct FHA business nationwide.

Prior to 1995, HUD required each mortgagee office to get approval from the FHA Field Office(s) located where the lender or mortgagee intended to submit mortgages for insurance endorsement.[2] After 1995, HUD expanded the geographic areas where lenders and mortgagees were allowed to conduct FHA business. The expansion allowed FHA Field Offices to create a ''lending area'' and permitted lenders and mortgagees to conduct business with several FHA Field Offices within that area. HUD required that lenders and mortgagees ''maintain at least one approved branch office within a 'lending area from which loans are submitted to the FHA Field Offices.'' [3] Currently, HUD follows its policy from HUD Handbook 4000.1 that was established in September of 2015. This policy calls a geographic area where a

[1] 88 FR 12906.

[2] *See* HUD, *Mortgagee Letter 95–36: Mortgagee Approval—Single Family Loan Production—Revised Mortgagee/Program Requirements,* Aug. 2, 1995, *https://www.hud.gov/sites/documents/DOC_20554.TXT.*

[3] *Id.; See also* HUD Handbook 4060.1 REV–1, *Mortgagee Approval Handbook I (4060.1)—Chapter 5 Part A. Branch Offices, https://www.hud.gov/sites/documents/40601C5HSGH.PDF.*

branch office is permitted to conduct FHA business an ''Area Approved for Business'' (AAFB).[4] HUD Handbook 4000.1 states that all branch offices that are registered with HUD are granted a nationwide AAFB to conduct FHA business; however, the registered branch ''may only exercise its authority to originate or underwrite FHA mortgages in those states where the lender or mortgagee fully complies with state origination and/or underwriting licensing and approval requirements.''

As the mortgage industry has evolved, HUD has found it necessary to update its regulations. In response to this change, HUD published a proposed rule on March 1, 2023, that would give lenders and mortgagees the option to register and maintain branch offices with HUD, which would allow them to be placed on HUD's Lender List Search page. In addition, the proposed rule would revise 24 CFR 202.5(i) to make fees applicable to each branch office that a lender or mortgagee registers with HUD, rather than applying fees to each branch office where they are authorized to conduct FHA business. These revisions were intended to reduce the administrative burden for existing lenders and mortgagees and eliminate barriers for entities interested in FHA programs. In addition to providing relief for the mortgage industry, HUD's proposed rule would provide the flexibility to encourage more lenders and mortgagees to originate FHA-insured mortgages. Removing the requirement to register branch offices will not affect HUD's monitoring of lenders and mortgagees. HUD will continue to maintain oversight and risk management of lenders and mortgagees who will remain responsible to FHA for the actions of its branch offices and employees.

In response to public comments as discussed further below, HUD is publishing this final rule without change from the proposed rule.

II. The Public Comments

HUD received 11 public comments on the proposed rule from various interested parties, including individuals, lenders and mortgagees, and business associations.

Support for the Rule

Numerous commenters supported finalizing the proposed rule.

Removing the branch office registration requirement is a needed update in response to industry developments resulting from technological changes and the COVID–19 Pandemic.

Commenters in support of the rule discussed the industry trend towards remote work. These commenters described a shift away from conducting FHA business in centralized workplaces to remote homes or smaller, less-centralized offices as a result of pre-pandemic technological developments and the COVID–19 pandemic shift to work from home. One commenter stated that remote work was likely to remain a part of the industry moving forward. Another comment stated that, due to remote work, their business had more locations that could possibly be considered branch offices based on the current rule.

HUD Response: HUD agrees with industry feedback that the requirement to register branch offices has become cumbersome and no longer aligns with the virtual environment in which the industry operates. Additionally, the requirement is somewhat redundant as branch offices will still need to be licensed by the state according to the Secure and Fair Enforcement for Mortgage Licensing Act of 2008 (12 U.S.C. 5101, *et seq.*) (SAFE Act). The rule may reduce administrative burden for existing lenders and mortgagees and eliminate barriers for entities interested in FHA programs.

Revising fee applicability to only branch offices registered with HUD will decrease costs.

One commenter stated that altering fee applicability to apply to only branch offices registered with HUD will lower lenders' overhead costs and maintain low FHA origination costs.

HUD Response: HUD agrees that the rule should reduce overhead costs of participating in FHA programs. The rule may also incentivize small size lenders, mortgagees, banks, and credit unions to offer FHA programs in branch offices in which they did not previously register with HUD. Expanding the availability of FHA programs to underserved urban and rural communities may provide homeowners with better access to FHA-insured mortgages and loans.

Eliminating this requirement will benefit homeowners by increasing access to FHA-insured products.

A commenter noted that the rule will likely increase the number of banks and credit unions participating in FHA programs and improve access for homeowners to FHA-insured mortgage products.

HUD Response: HUD agrees that removing the requirement to register branch offices with HUD will provide lenders and mortgagees greater flexibility and removes a burdensome administrative and financial burden when participating in FHA programs.

As branch offices are subject to state licensing, HUD's current requirement for branch office registration is unnecessary.

One commenter said that under the Secure and Fair Enforcement of Mortgage Licensing Act of 2008 (SAFE Act), branch offices are still subject to state licensing, so HUD's branch office registration requirement is unnecessary and removing the requirement will not affect HUD's monitoring of mortgagees.

HUD Response: HUD agrees and is revising its branch registration requirements because all lenders and mortgagees must comply with state licensing and approval requirements. Further, lenders and mortgagees can only exercise the authority to conduct FHA business from those branch office locations in which they fully comply with state licensing and approval requirements for origination, underwriting and/or servicing. Therefore, the current requirement to also register branch offices with HUD has become redundant. Removing the branch office registration requirement will not affect HUD's monitoring. HUD can monitor lenders and mortgagees even without the specific branch office identification, and lenders and mortgagees will still remain responsible to FHA for the actions of its branch offices and employees.

Self-regulation by lenders will prevent unregistered branch offices from becoming non-compliant with applicable laws.

A commenter stated that branch offices will still be overseen by ''home'' offices motivated by licensing requirements and business reputation to ensure branch offices remain compliant. The commenter also stated that a lender's compliance could still be enforced through the audit process and, as lenders regularly submit loan files to FHA, any later attempts by these lenders to alter records will alert regulators of non-compliance.

HUD Response: HUD agrees and notes that while it will continue to maintain oversight and risk management of lenders and mortgagees, it is the responsibility of each lender and mortgagee to ensure compliance with all FHA program requirements. Each lender and mortgagee is responsible for the actions of its staff that participate in FHA transactions. Each lender and mortgagee must continue to maintain effective internal controls and execute risk and control procedures on a day-to-day basis. Further, HUD has existing processes and procedures for

[4] *See* HUD Handbook 4000.1 I.A.4b, *Single Family Lending Area (4000.1), https://www.hud.gov/sites/dfiles/OCHCO/documents/4000.1hsgh-080923.pdf.*

enforcement activities to address noncompliance.

FHA lenders will continue to be monitored by HUD's Office of Lender Activities and Program Compliance—Quality Assurance Division.

One commenter stated that the rule states that FHA lenders will continue to be monitored by HUD's Office of Lender Activities and Program Compliance—Quality Assurance Division. The commenter stated that, as a result, HUD will still review the level of early defaults and claims on mortgages originated from each lender or mortgagee in a HUD field office's geographic area. The commenter stated lenders and mortgagees with excessive rates of early default and claims could then have their authority terminated by FHA.

HUD Response: The rule does not affect HUD's monitoring of lenders and mortgagees. Further HUD's Office of Lender Activities and Program Compliance—Quality Assurance Division will continue to monitor FHA mortgagees quarterly to determine whether Credit Watch Termination is warranted.

Opposition to the Rule

Some commenters opposed this rule without providing a basis for their opposition.

HUD Response: HUD is unable to address commenters' opposition to the rule, as they did not provide specific reasons for their opposition.

Concerns With the Rule

There is a potential for lenders to become lax in complying with applicable regulations if branch offices are not registered.

One commenter said that while they welcome the rule, it could result in lenders becoming less compliant if branch offices are not registered with HUD. The commenter stated that if offices were no longer subject to branch inspections, lenders will be less likely to hold branch office employees accountable.

HUD Response: HUD appreciates this comment and the concern raised. However, as stated previously in this preamble, each lender and mortgagee has, and will continue to have, the responsibility to manage its risk, to comply with regulations and standards, and to carry out its defined risk management processes. HUD will continue its proactive monitoring of the performance for lenders and mortgagees. Further, HUD has existing processes and procedures for enforcement activities to address noncompliance.

There should be limitations on what an unregistered branch office can and cannot do.

One commenter expressed concern with reduced compliance by unregistered branch offices and suggested imposing limitations on what an unregistered branch office can and cannot do.

HUD Response: HUD does not agree that a bifurcation between the permitted activities for registered and unregistered branch offices is necessary. Each lender and mortgagee has been, and will continue to be, responsible for the actions of its staff that participate in FHA transactions. Further lenders and mortgagees must continue to exercise control over the management and supervision of such staff, which must include regular and ongoing reviews of staff performance and of the work performed. Performance monitoring will include FHA activity from both registered and unregistered branch offices. Further, HUD currently has existing processes and procedures for enforcement activities to address noncompliance.

Questions about HUD's current practices and implementation of the rule.

One commenter questioned ''if eliminating the requirement that lenders register all branch offices conducting FHA business will affect reporting Neighborhood Watch/Compare Ratio Data by branch office and, if so, if it will skew the data by excessively expanding the dataset to larger geographic parameters results?'' The commenter stated concerns about how FHA will record branch level data without individual branch office registration.

Another commenter had various questions regarding HUD's current practices and implementation of the proposed rule including: ''1. [d]oes HUD currently monitor excessive rates of early defaults and claims based on the branch ID or mortgages originated within the geographic area served by a HUD field office?'' ''2. If HUD monitors based on the geographic area served by a HUD field office, and FHA terminates the lender's authority, does that termination apply to the entire geographic area served by a HUD field office, regardless of how many branches serve that area, or just the branch with the excessive rate of early defaults and claims in that geographic area?'' ''3. If HUD monitors based on excessive rate of early defaults and claims by branch ID, what would happen if an institution only had one branch registered under the proposed rule?'' ''Would the entire institution be terminated, or would the institution be terminated in that specific geographic area where an excessive rate of early defaults and claims occurred?'' ''4. If a lender chooses to have multiple branch IDs, would HUD require the registered branch manager to be physically located somewhere within the geographic area served by a HUD field office based on the branch's physical address?'' ''5. If so, what would HUD's expectation be for those call center branches where the employees work remotely?'' ''In that instance, would the required office address be the home office?'' ''Would HUD permit a branch manager to be listed under multiple lender branch IDs (for the same lender) or would the need for a branch manager be removed altogether, permitting a lender ''manager'' assigned by lender ID?''

HUD Response: Once the rule becomes effective, FHA branch registration will become optional. Mortgagees that elect to register branch offices will still be able to access branch-level data in Neighborhood Watch, including Compare Ratios for registered branches. For mortgagees that discontinue branch office registration or that never had a business model that included local or regional branch offices, Neighborhood Watch provides a variety of geographic parameters independent of branch IDs. Most FHA monitoring processes already focus on mortgagee-level data based on a variety of geographic areas. For example, FHA's current Credit Watch Termination process focuses on properties underwritten by each Direct Endorsement Mortgagee in a particular HUD field office jurisdiction, regardless of the originating branch. FHA expects mortgagees to conduct similar analysis, and to continue tracking the performance of specific branches using their own data if necessary.

HUD currently monitors excessive rates of early defaults and claims based on mortgages originated/underwritten within the geographic area served by a HUD field office. When FHA terminates a mortgagee's authority through the Credit Watch Termination process, that termination applies to the entire geographic area served by the HUD field office, regardless of how many branches serve that area.

Currently, HUD defines a branch manager as an onsite manager for a branch office who manages one branch office. HUD defines a regional manager as a manager who oversees the operation of multiple branch offices. Each lender and mortgagee must have a branch and/or regional manager to oversee each of its branch offices. Furthermore, each lender and mortgagee must ensure that it and its employees

comply with the requirements of the SAFE Act, including the licensing and registration of its employees in the Nationwide Mortgage Licensing System (NMLS).

III. Findings and Certifications

Regulatory Review—Executive Orders 12866, 13563, and 14094

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by the Office of Management and Budget (OMB) in accordance with the requirements of the order. Executive Order 13563 (Improving Regulation and Regulatory Review) directs executive agencies to analyze regulations that are ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter referred to as the ''Modernizing E.O.'') amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review), among other things.

The final rule will revise 24 CFR 202.5 (i) and (k) to update HUD's regulation to conform with the mortgage industry's evolving business practices. Additionally, the rule will lessen the administrative burden on lenders and mortgagees. This rule was determined not to be a ''significant regulatory action'' as defined in section 3(f) of Executive Order 12866 as amended by Executive Order 14094 and is not an economically significant regulatory action and therefore was not subject to OMB review.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4; approved March 22, 1995) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This final rule does not impose any Federal mandates on any state, local, or tribal government, or on the private sector, within the meaning of the UMRA.

Environmental Review

This final rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The rule will remove the requirement that lenders and mortgagees register with HUD each branch office where they conduct FHA business. This will not create an undue burden on small entities, instead it will eliminate the burden for all lenders and mortgagees of having to register branch offices with HUD and pay the associated fees. HUD has determined that this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has Federalism implications if the rule either imposes substantial direct compliance costs on state and local governments or is not required by statute, or the rule preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule will not have Federalism implications and will not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless the collection displays a currently valid Office of Management and Budget (OMB) control number. The information collection requirements contained in this final rule have been approved by OMB under the Paperwork Reduction Act and assigned OMB control number 2502–0059.

List of Subjects in 24 CFR Part 202

Administrative practice and procedure, Home improvement, Manufactured homes, Mortgage insurance, Reporting, and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble above, HUD amends 24 CFR part 202 as follows:

PART 202—APPROVAL OF LENDING INSTITUTIONS AND MORTGAGEES

■ 1. The authority citation for part 202 continues to read as follows:

Authority: 12 U.S.C. 1703, 1709 and 1715b; 42 U.S.C. 3535(d).

§ 202.5 [Amended]

■ 2. Amend § 202.5 by:
■ a. In paragraph (i) removing ''authorized to originate Title I loans or submit applications for mortgage insurance'' and adding in its place ''that the lender or mortgagee registers with the Department'';
■ b. In paragraph (k), adding ''or mortgagee'' after ''A lender'' in the first sentence of paragraph (k), and removing the second sentence.

Julia R. Gordon,

Assistant Secretary of Office of Housing—Federal Housing Administration.

[FR Doc. 2024–02023 Filed 2–1–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF JUSTICE

28 CFR Parts 0 and 27

[Docket No. JMD 154; AG Order No. 5872–2024]

RIN 1105–AB47

Whistleblower Protection for Federal Bureau of Investigation Employees

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This rule updates the Department of Justice (''Department'') regulations on the protection of whistleblowers in the Federal Bureau of Investigation (''FBI''). This update reflects changes resulting from an assessment conducted by the Department in response to Presidential Policy Directive–19 of October 10, 2012, ''Protecting Whistleblowers with Access to Classified Information'' (''PPD–19''), and the Federal Bureau of Investigation Whistleblower Protection Enhancement Act of 2016 (''FBI WPEA of 2016''). This

rule updates the description of protected whistleblower disclosures and covered personnel actions to conform to the FBI WPEA of 2016; provides for more equal access to witnesses; and specifies that compensatory damages may be awarded as appropriate. This rule also adds new provisions to formalize practices that have been implemented informally, including providing for the use of acknowledgement and show-cause orders, providing access to alternative dispute resolution (''ADR'') through the Department's FBI Whistleblower Mediation Program, clarifying the authority to adjudicate allegations of a breach of a settlement agreement, and reporting information about those responsible for unlawful reprisals. This regulation reiterates that the determinations by the Director of the Office of Attorney Recruitment and Management (''OARM'') must be independent and impartial.

DATES: Effective March 4, 2024.

FOR FURTHER INFORMATION CONTACT: Morton J. Posner, General Counsel, Justice Management Division; email: *Morton.J.Posner@usdoj.gov;* telephone: 202–514–3452; Michael E. Stamp, Acting Director, Office of Attorney Recruitment and Management; email: *Michael.E.Stamp@usdoj.gov;* telephone: 202–598–7772.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

On November 1, 1999, the Department issued a final rule entitled ''Whistleblower Protection For Federal Bureau of Investigation Employees,'' published in the **Federal Register** at 64 FR 58782, establishing procedures under which (1) FBI employees or applicants for employment with the FBI may make disclosures of information protected by the Civil Service Reform Act of 1978, Public Law 95–454 (''CSRA''), and the Whistleblower Protection Act of 1989 (''WPA''), Public Law 101–12; and (2) the Department will investigate allegations by FBI employees and applicants for employment of reprisal for making such protected disclosures and take appropriate corrective action. The rule is codified at 28 CFR part 27.

On January 9, 2008, the Department updated part 27 as well as 28 CFR 0.29d primarily to conform to organizational changes brought about by a restructuring of relevant offices of the FBI. Technical Amendments to the Regulations Providing Whistleblower Protection for Federal Bureau of Investigation Employees, 73 FR 1493.

On October 10, 2012, President Barack Obama issued PPD–19, which, in part, directed that the Department prepare a report that (1) assesses the efficacy of the Department's FBI whistleblower protection regulations found in 28 CFR part 27 in deterring the personnel practices prohibited in 5 U.S.C. 2303, and in ensuring appropriate enforcement of section 2303, and (2) describes any proposed revisions to those regulations that would increase their effectiveness in fulfilling the purposes of section 2303. PPD–19 at 5.

In response to this directive, the Office of the Deputy Attorney General conducted a comprehensive review of the Department's whistleblower regulations and historical experience with their operation.[1] As part of that process, the Department formed a working group, seeking participation from the other key participants in administering the Department's FBI whistleblower regulations—the FBI, OARM, the Office of the Inspector General, and the Office of Professional Responsibility—as well as the Justice Management Division. In addition, the Department consulted with the Office of Special Counsel (''OSC'') and FBI employees, as required by PPD–19. The Department also consulted with representatives of non-governmental organizations that support whistleblowers' rights and with private counsel for whistleblowers (collectively, whistleblower advocates).[2]

With respect to consultation with FBI employees, the FBI's representatives on the Department's working group consulted with various FBI entities: the Ombudsman; the Office of Equal Employment Opportunity Affairs; the Office of Integrity and Compliance; the Office of Professional Responsibility; the Human Resources Division; and the Inspection Division. The representatives also solicited the views of each of the FBI's three official advisory committees that represent FBI employees—the All-Employees Advisory Committee, the Agents Committee, and the Middle-Management Committee.

In April 2014, after completion of the PPD–19 review, the Department issued a report, ''Department of Justice Report on Regulations Protecting FBI Whistleblowers'' (''PPD–19 Report''). The report considered the historical context of the Department's efforts to protect FBI whistleblowers from reprisal and the Department's current policies and procedures for adjudicating claims of reprisal against FBI whistleblowers; summarized and analyzed statistics regarding the use of these policies and procedures in recent years; and identified desired changes to existing policies and procedures as a result of this assessment.

The Department issued a notice of proposed rulemaking on March 29, 2023, to reflect the PPD–19 Report's findings and recommendations, as modified to comply with the FBI WPEA of 2016, discussed in further detail below, which President Obama signed on December 16, 2016.

II. Historical Background on FBI Whistleblower Protection

Legislative protection of civilian Federal whistleblowers from reprisal began in 1978 with passage of the CSRA, and was expanded by the WPA and the Whistleblower Protection Enhancement Act of 2012, Public Law 112–199 (''WPEA of 2012''). Currently, Federal employees fall into three categories. Most civilian Federal employees are fully covered by the statutory regime established by the CSRA, which permits them to challenge alleged reprisals through the OSC and the Merit Systems Protection Board (''MSPB''). By contrast, some Federal agencies that deal with intelligence are expressly excluded from the whistleblower protection scheme established by these statutes.

The FBI is in an intermediate position: Although it is one of the agencies expressly excluded from the scheme established for Federal employees generally, its employees nevertheless are protected by a separate statutory provision and special regulations promulgated pursuant to that provision, which forbid reprisals against FBI whistleblowers and provide an administrative remedy within the Department. *See* 28 CFR part 27.

To elaborate, the CSRA sets forth ''prohibited personnel practices,'' which are a range of personnel actions that the Federal Government may not take against Federal employees. One such prohibited personnel practice is retaliating against an employee for revealing certain agency information. Specifically, the CSRA originally made it illegal for an agency to take or fail to take a personnel action with respect to any employee or applicant for employment as a reprisal for disclosure

[1] On November 27, 2012, President Obama signed the Whistleblower Protection Enhancement Act of 2012, Public Law 112–199, (''WPEA of 2012''). The Department considered the WPEA of 2012 as part of its PPD–19 review.

[2] The Department convened a meeting with the following whistleblower advocate organizations: Project on Government Oversight; Kohn, Kohn & Colapinto; Government Accountability Project; American Civil Liberties Union; and a former chief counsel to the chairman of the Merit Systems Protection Board.

of information that the employee or applicant reasonably believed evidenced a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. Public Law 95–454, sec. 101(a), codified at 5 U.S.C. 2302(b)(8). The CSRA also created the MSPB and OSC to enforce the prohibitions on specified personnel practices.

The CSRA, however, expressly excluded from this scheme the FBI, the Central Intelligence Agency, various intelligence elements of the Department of Defense, and any other executive agency or unit thereof as determined by the President with the principal function of conducting foreign intelligence or counterintelligence activities. Public Law 95–454, sec. 101(a), codified at 5 U.S.C. 2302(a)(2)(C)(ii).

For the FBI alone, the CSRA specifically prohibited taking a personnel action against employees or applicants for employment as a reprisal for disclosing information that the employee or applicant reasonably believed evidenced a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. *Id.*, codified at 5 U.S.C. 2303(a)(1), (2). The CSRA defined a ''personnel action'' for the purpose of the FBI-specific prohibition as any action specifically described in clauses (i) through (x) of 5 U.S.C. 2302(a)(2)(A), taken with respect to an employee in—or an applicant for—a position other than one of a confidential, policy-determining, policymaking, or policy-advocating character. *Id.*, codified at 5 U.S.C. 2303(a). In addition, the CSRA limited the protection of the FBI-specific prohibition to only those disclosures that the FBI employee made through narrowly defined internal channels—*i.e.*, to the Attorney General or the Attorney General's designee. *Id.* Finally, the CSRA directed the President to provide for the enforcement of the provision relating to FBI whistleblowers in a manner consistent with applicable provisions of 5 U.S.C. 1206, the section of the CSRA that originally set out the responsibilities of the OSC, the MSPB, and agency heads in response to a whistleblower complaint and provided for various remedies. *Id.*, codified at 5 U.S.C. 2303(c).

In April, 1980, the Department published a final rule implementing section 2303. The rule provided, among other things, for a stay of any personnel action if there were reasonable grounds to believe that the personnel action was taken, or was to be taken, as a reprisal for a disclosure of information by the employee to the Attorney General or the Attorney General's designee that the employee reasonably believed evidenced wrongdoing covered by section 2303. Office of Professional Responsibility; Protection of Department of Justice Whistleblowers, 45 FR 27754, 27755 (Apr. 24, 1980).

In 1989, the statutory scheme for most civilian employees changed in some respects when Congress passed the WPA, which significantly expanded the avenues of redress generally available to civilian Federal employees. In doing so, it replaced section 1206 with sections 1214 and 1221; these new sections set forth the procedures under which OSC would investigate prohibited personnel practices and recommend or seek corrective action, and the circumstances under which an individual right of action before the MSPB would be available. Public Law 101–12, sec. 3. Consistent with this change, the WPA amended section 2303, governing FBI whistleblowers, to replace the requirement that enforcement of whistleblower protections be consistent with applicable provisions of section 1206 with a requirement that enforcement be consistent with applicable provisions of newly added sections 1214 and 1221. Public Law 101–12, sec. 9(a)(1).

The WPA also amended the regime generally applicable to civil service employees by revising section 2302 to protect only disclosures of information the employee reasonably believes evidences ''gross mismanagement,'' rather than ''mismanagement,'' as originally provided by the CSRA. Public Law 101–12, sec. 4(a). However, the WPA did not make a corresponding change to section 2303, the statute applicable to FBI whistleblowers.

On April 14, 1997, President William J. Clinton issued a memorandum delegating to the Attorney General the functions concerning employees of the FBI vested in the President by the CSRA, and directing the Attorney General to establish appropriate processes within the Department to carry out these functions. Delegation of Responsibilities Concerning FBI Employees Under the Civil Service Reform Act of 1978, 62 FR 23123 (Apr. 28, 1997). In November, 1999, the Department published a final rule establishing procedures under which FBI employees or applicants for employment may make disclosures of wrongdoing. 64 FR 58782 (Nov. 1, 1991). The rule created a remedial scheme within the Department through which FBI employees can seek redress when they believe they have suffered reprisal for making a protected disclosure. Subject to minor amendments in 2001 and 2008, the rule, codified at 28 CFR part 27, remains in force.

On November 27, 2012, the month following President Obama's issuance of PPD–19, he signed the WPEA of 2012 into law. That act, among other things, amended 5 U.S.C. 1214 and 5 U.S.C. 1221 to authorize awards of compensatory damages. Although the FBI is expressly excluded from coverage under these statutory provisions and is instead covered by 5 U.S.C. 2303, section 2303 directs that the President ensure enforcement of section 2303 in a ''manner consistent with the applicable provisions of sections 1214 and 1221.'' 5 U.S.C. 2303(c). The WPEA of 2012 also expanded the number of prohibited personnel actions set out in section 2302(a)(2), but made no corresponding change to the cross-reference in section 2303(a). Accordingly, the Department has considered the WPEA of 2012's changes to sections 1214, 1221, and 2302(a) and their impact on the FBI's whistleblower protection program under section 2303 and has concluded that corresponding technical amendments to the current regulations are appropriate, as described further below.

On December 16, 2016, President Obama signed Public Law 114–302, the FBI WPEA of 2016. That statute made two changes to the statutory whistleblower protection scheme applicable to FBI employees. First, it expanded the list of recipients set forth in 5 U.S.C. 2303(a) to whom a disclosure could be made to be protected (assuming the substantive requirements are met). Protected disclosures now may be made to an employee's supervisor in the employee's direct chain of command, up to and including the Attorney General; the Inspector General; the Department's Office of Professional Responsibility; the FBI Office of Professional Responsibility; the FBI Inspection Division; Congress, as described in 5 U.S.C. 7211; OSC; or an employee designated to receive such disclosures by any officer, employee, office, or division of the listed entities. *See* Public Law 114–302, sec. 2.

Second, the FBI WPEA of 2016 changed the substantive requirement for a protected disclosure, requiring that the disclosure be one that the discloser reasonably believes evidences ''any violation'' (previously, ''a violation'') of any law, rule, or regulation, or ''gross mismanagement'' (previously, just ''mismanagement''), in addition to the

previous (and unchanged) provision for disclosures of a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety. *Id.*

On December 23, 2022, President Joseph Biden signed Public Law 117–263, which amended 5 U.S.C. 2303 to afford FBI whistleblowers with the right to (1) appeal a final determination or corrective action order to the MSPB, and (2) subject to certain conditions, seek corrective action directly from the MSPB pursuant to 5 U.S.C. 1221. Public Law 117–263, sec. 5304(a), codified at 5 U.S.C. 2303(d)(1), (2).

Finally, on March 29, 2023, the Department published a proposed rule, which intended to (1) improve, pursuant to PPD–19 and consistent with the Department's recommendations in the PPD–19 Report, the internal investigation and adjudication of whistleblower retaliation claims by FBI employees and applicants for employment under the remedial scheme initially established in 1999 and codified at 28 CFR part 0 and part 27; and (2) ensure that this process is consistent with changes enacted by the WPEA of 2012 and the FBI WPEA of 2016. *See* 88 FR 18487 (March 29, 2023). Through the proposed rule, the Department invited specific comments on and recommendations for how the Department might further revise the regulations to increase fairness, effectiveness, efficiency, and transparency, including to provide enhanced protections for whistleblowers, in addition to the proposed changes. *Id.*

III. Comments to the Proposed Rule and Department Responses

Following a period for public comment on the March 29, 2023, proposed rule, the Department received a number of comments, many of which generally endorsed the rulemaking proposal. Comments on the proposed rule, and the Department's responses, are included in this section, where they apply to specific subsections of the rule.

Definition of a ''Protected Disclosure''

In the proposed rule, the Department proposed several changes to the definition of a ''protected disclosure'' under 28 CFR 27.1(a) to conform to the requirements of the FBI WPEA of 2016. Under the current rule, 28 CFR 27.1(a), a disclosure is considered protected if (1) it was made to an office or individual designated to receive a protected disclosure, and (2) the person making the disclosure reasonably believed the disclosure evidenced a specific type of wrongdoing listed in § 27.1(a)(1) and (a)(2). The current rule lists the following entities and individuals as designated recipients of a protected disclosure:

- the Department's Office of Professional Responsibility;
- the Department's Office of the Inspector General;
- the FBI Office of Professional Responsibility;
- the FBI Inspection Division Internal Investigations Section;
- the Attorney General;
- the Deputy Attorney General;
- the Director of the FBI;
- the Deputy Director of the FBI; or
- the highest ranking official in any FBI field office.

The proposed rule proposed to expand the list to comply with the change made by the FBI WPEA of 2016. Specifically, the proposed amendment to § 27.1(a) would require that, to be protected, a disclosure must be made to:

- a supervisor in the direct chain of command of the employee, up to and including the Attorney General;
- the Department's Inspector General;
- the Department's Office of Professional Responsibility;
- the FBI Office of Professional Responsibility;
- the FBI Inspection Division;
- Congress, as described in 5 U.S.C. 7211;
- OSC; or
- an employee of any of the above entities, when designated by any officer, employee, office, or division thereof for the purpose of receiving such disclosures.

With respect to § 27.1(a)(2), the current rule requires that the person making the disclosure reasonably believe that it evidences: ''Mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.'' In the proposed rule, the Department proposed to amend § 27.1(a)(2) to conform to the FBI WPEA of 2016 by removing ''Mismanagement'' and replacing it with ''Gross mismanagement.''

Several commenters expressed concern with the revised definition of a ''protected disclosure'' under 28 CFR 27.1(a) in the proposed rule. One commenter expressed concern with the expanded list of offices and officials designated to receive a protected disclosure under 28 CFR 27.1(a) in the proposed rule, noting that additional recipients ''may result in a game of telephone where information may be misconstrued when it gets passed up the chain.'' Another commenter wanted to remove the limited list of recipients entirely. Several commenters expressed concern with the proposed change to § 27.1(a)(2) to remove ''Mismanagement'' and replace it with ''Gross mismanagement.'' These commenters were concerned that the change would narrow the protections currently afforded FBI whistleblowers or create difficulties in interpretation.

Notwithstanding these concerns, the Department adopts in this final rule the changes to 28 CFR 27.1(a) set forth in the proposed rule. The designated recipients for protected disclosures are mandated by statute, as is the requirement that only ''gross mismanagement''—as opposed to any other type of ''mismanagement''—constitutes a protected disclosure under the FBI WPEA of 2016, 5 U.S.C. 2303(a)(1) and (a)(2)(B). Because the purpose of this proposed rule is to conform 28 CFR part 27 to the FBI WPEA of 2016, the Department declines to adopt the changes sought by the commenters.

Modifying the Definition of a ''Personnel Action''

One commenter suggested amending the ''personnel action'' definition under 28 CFR 27.2(b) to include all twelve actions currently listed in 5 U.S.C. 2302(a)(2)(A). The Department notes that this final rule updates the description of protected whistleblower disclosures and covered personnel actions to conform to the FBI WPEA of 2016. The commenter also suggested that the Department further expand the definition of ''personnel action'' in the rule to include retaliatory investigations and the denial, suspension, or revocation of a security clearance. Because the term ''personnel action'' is defined in 5 U.S.C. 2302(a)(2)(A), and the purpose of this proposed rule is to conform 28 CFR part 27 to the FBI WPEA of 2016, the Department declines to adopt this suggestion.

Statement of Independence and Impartiality of OARM Determinations

During the Department's PPD–19 review, whistleblower advocates expressed concern with the internal Department adjudication of FBI reprisal cases brought under part 27. To address this concern, the Department added language to 28 CFR 27.4(e)(1) in the proposed rule that the determinations by the Director of OARM (''OARM Director'') shall be independent and impartial.

One commenter suggested that the rule be further updated to apply the statement of independence and impartiality to the OARM Director's decision on a Conducting Office's request to stay a personnel action under

28 CFR 27.4(b). That provision states, in relevant part: ''[T]he Conducting Office may request the Director to order a stay of any personnel action for 45 calendar days if it determines that there are reasonable grounds to believe that a reprisal has been or is to be taken. The Director shall order such stay . . . unless the Director determines that, under the facts and circumstances involved, such a stay would not be appropriate.'' Section 27.4(d) similarly addresses the OARM Director's authority to grant a complainant's request for a stay of a personnel action ''if the Director determines that such a stay would be appropriate.''

Because the commenter's request for a statement of the OARM Director's independent and impartial determination on a request for a stay of a personnel action is consistent with the concerns raised by whistleblower advocates during the Department's PPD–19 review regarding the OARM Director's determinations under § 27.4(e), the Department adopts the commenter's suggestion, and also applies it to § 27.4(d). This final rule thus changes § 27.4(e)(1) to read: ''The determination made by the Director under this section shall be independent and impartial.''

Right to a Hearing

One commenter recommended that the rule provide a party with the right to a hearing after OARM finds that it has jurisdiction over a matter. Presently, neither party has an automatic right to a hearing before the OARM Director; however, under § 27.4(e)(3), either party may request a hearing. The OARM Director currently has the discretion to grant or deny a party's request for a hearing. Under current practice, the request will be granted when the complainant has presented a cognizable legal claim and there are disputed issues of material fact that need resolution through live, testimonial evidence. In determining whether a hearing is appropriate in a particular case, the OARM Director currently considers whether a hearing would result in unnecessary delay, needless expenditure of administrative resources, or unnecessary burdens on the parties, and whether live testimony or argument would be helpful in reaching a decision. The Department concludes that automatically granting a right to a hearing after a finding of OARM jurisdiction would not be an efficient means of resolving all matters over which OARM has jurisdiction. The Department therefore declines to adopt the recommendation.

Equalizing Access to Witnesses

During the Department's PPD–19 review, whistleblower advocate groups raised concerns that, in some cases, the FBI has obtained evidence from FBI management officials or employees as witnesses, either through affidavits or testimony at a hearing, but that complainants were unable to obtain similar access to FBI witnesses, particularly former employees. Because the OARM Director lacks the authority to compel attendance at a hearing, appearance at a deposition, or the production of documentary evidence from individuals not currently employed by the Department, the groups asked the Department to consider implementing a regulatory provision that would help equalize access to witnesses. Because the Department agreed with that concern, the Department added a sentence to 28 CFR 27.4(e)(3) in the proposed rule to give the OARM Director the discretion to prohibit a party from adducing or relying on evidence from a person whom the opposing party does not have an opportunity to examine or to give less weight to such evidence.

Two commenters suggested changes to the proposed rule that would eliminate the OARM Director's discretion and automatically preclude the use of evidence that complainants do not have access to or relying on evidence from a witness the opposing party is unable to examine.

In the Department's view, eliminating the Director's discretion by requiring that unavailable witnesses be excluded in all cases would unfairly disadvantage whistleblowers when, through no fault of their own, witnesses who initially provided affidavits or other evidence in support of the whistleblower later become unable or unwilling to cooperate further. Under the proposed rule, depending on the circumstances of each case, the Director may exercise discretion in allowing a whistleblower to present such evidence, despite the witness's unavailability to the FBI. Because the exercise of discretion is necessary to conduct fair and just proceedings, the Department declines to adopt the suggestion to eliminate the OARM Director's discretion regarding how best to address the parties' unequal access to witnesses.

Another commenter expressed a concern that the OARM Director's discretion in the proposed revision to 28 CFR 27.4(e)(3) should include stipulations, or, alternatively, a standard specifying the circumstances in which the OARM Director would exercise his or her discretion.

The Department agrees that it should describe some of the factors that the OARM Director will consider when exercising the OARM Director's discretion. But because we cannot know with certainty the circumstances in which the OARM Director may decide to prohibit a party from relying on witness evidence when the other party did not have equal access to it, the Department declines to adopt the commenter's suggestion as proposed. The Department will, however, modify § 27.4(e)(3) in the final rule to specify some factors that the OARM Director may consider in the OARM Director's decision to exclude such evidence.

One commenter agreed with the proposed provision, but asserted that the Department should implement adequate security to protect witnesses from possible reprisal. OARM currently uses procedures that protect certain information obtained during the course of discovery containing personally identifiable information that could potentially impair the safety or privacy rights of past and current employees. OARM's protective procedures include the use of protective orders, redaction of documents, and closed hearings for the presentation of any live testimonial evidence. Given the OARM procedures already in place, the Department declines to adopt this suggestion.

Finally, one commenter suggested that the rule be modified to require the FBI to attempt to secure the testimony from employees in Federal service who are employed by other Federal agencies at the time of adjudication of the whistleblower reprisal complaint.

Requiring the FBI to attempt to secure the testimony from Federal employees working at other Federal agencies, however, would require the FBI to communicate directly with potentially adverse witnesses on behalf of complainants. The proposed rule helps to equalize the parties' access to witnesses. The commenter's suggested change does not further that goal. The Department declines to adopt this suggestion.

Acknowledgement and Show-Cause Orders

In the proposed rule, the Department added a new paragraph (f) to § 27.4 to formalize the OARM Director's existing practice of issuing acknowledgement and show-cause orders similar to those issued by the MSPB. Under proposed 28 CFR 27.4(f)(1), the acknowledgment orders issued by the OARM Director shall include: information on the relevant case processing procedures and timelines, including the manner of designation of a representative; the time

periods for and methods of discovery; the process for resolution of discovery disputes; and the form and method of filing of pleadings. The proposed provision further specified that the Acknowledgement Order shall inform the parties of the jurisdictional requirements for full adjudication of the request for corrective action and their respective burdens of proof.

In cases where the OARM Director determines that there is an initial question of the OARM Director's jurisdiction to review a request for corrective action, the OARM Director shall issue, along with the Acknowledgement Order, a Show-Cause Order explaining the grounds for such determination and directing that, within 10 calendar days of receipt of the order, the complainant submit a written response explaining why the request should not be dismissed for lack of jurisdiction. The FBI's reply to the complainant's response to the Show-Cause Order is due within 20 calendar days within its receipt of the complainant's response under proposed § 27.4(f)(3).

Two commenters suggested an extension of the 10-calendar day deadline for the complainant's response to the Show-Cause Order under § 27.4(f)(2). The Department adopts the proposal to extend that deadline and modifies § 27.4(f)(2) of this final rule to provide the complainant with 15 calendar days to respond to a Show-Cause Order.

Damages

One commenter suggested modifying 28 CFR 27.4(g) in the proposed rule to make an award of attorney's fees and costs mandatory whenever corrective action is ordered.

Section 27.4(f) currently provides the OARM Director with the authority to order certain corrective action to place the complainant, as nearly as possible, in the position he or she would have been in had the reprisal not taken place. Such corrective action ''may include,'' but is not limited to, reimbursement for attorney' fees and reasonable costs. Under section 2303(c), the Department is charged with enforcing 28 CFR part 27 ''consistent with applicable provisions of 1214 and 1221.'' Corrective action ordered by the MSPB to a prevailing party in an Individual Right of Action appeal under 5 U.S.C. 1221(g)(1)(B) ''shall include'' attorney's fees and costs provided that other requirements are met. Because the Department already enforces its corrective action authority in FBI whistleblower cases ''consistent with'' section 1221(g)(1)(B), and there are circumstances where an award of attorney's fees would not be mandatory (*e.g.,* where the complainant is a pro se litigant), the Department declines to adopt this suggestion as stated. However, this final rule, in new § 27.4(g), authorizes the OARM Director to order corrective action to a prevailing complainant that ''shall, as appropriate,'' include attorney's fees and reasonable costs, among other things.

Transparency Regarding OARM and Deputy Attorney General Decisions, and the Publication of Reprisal Findings

In the proposed rule, the Department added § 27.4(h) to formalize OARM's policy of forwarding to the FBI Office of Professional Responsibility, the FBI Inspection Division, and the FBI Director a copy of the final determination in cases where the OARM Director finds reprisal.

One commenter endorsed the proposal, but suggested that the Department also report findings of reprisal to ''any other appropriate law enforcement authority.''

Under current practice, the OARM Director refers findings of reprisal internally within the FBI, and, as discussed below, the Department has decided to publish in redacted form all dispositive OARM decisions and Deputy Attorney General decisions reversing or remanding OARM decisions, including those involving reprisal findings. The Department believes these actions will help to hold those responsible for unlawful reprisal accountable and deter others from violating the protections afforded FBI whistleblowers. Because there is no other ''law enforcement authority'' that would accomplish these goals, the Department declines to adopt this recommendation.

Another commenter endorsed the proposal, but suggested that internal reporting alone is likely insufficient to deter retaliatory conduct by FBI officials. The commenter suggested that the Department consider publishing redacted or sanitized findings ''to ensure that [the] individuals responsible understand the importance of respecting whistleblower protections and the significant consequences for violating them.'' Two other commenters also recommended that the proposed regulation require that OARM publish its decisions, and one suggested prohibiting OARM from citing or relying on a citation to an unpublished decision that all parties do not have access to.

In response, the Department has decided to publish in redacted form any decisions in closed cases on the merits, as well as procedural decisions showing how the OARM Director and the Deputy Attorney General have analyzed and decided issues relating to jurisdiction, discovery, merits, corrective relief, and other issues of relevance to FBI whistleblowers. All future decisions meeting these criteria will be made public in redacted form, as will decisions issued after January 1, 2018. This is a Departmental policy decision, subject to revision or rescission, and is therefore not memorialized in this final rule. The Department also adopts the recommendation to specify in this final rule, in a new § 27.4(j), that the OARM Director will not specifically cite or rely on any unpublished FBI whistleblower decisions in OARM issuances.

Expanding the Availability of ADR

In the proposed rule, the Department proposed to add 28 CFR 27.7 (§ 27.8 in this final rule) to formalize inclusion of the Department's FBI Whistleblower Mediation Program, which was implemented in 2014. One commenter suggested that the provision be modified to expand the availability of ADR to ''unprotected or potential'' whistleblowers who have not obtained ''protected status'' under 28 CFR part 27.

As discussed in the proposed rule, mediation through the FBI Whistleblower Mediation Program may be requested by the complainant at any stage of proceedings under 28 CFR part 27—*i.e.,* from the initial filing of the complaint with the Conducting Office and at any subsequent point thereafter while the complaint is being investigated or adjudicated. The rule does not require that the complainant be deemed a ''protected'' whistleblower by the OARM Director under the adjudicative procedures set forth in 28 CFR 27.4 before electing ADR through the FBI Whistleblower Mediation Program. However, the FBI Whistleblower Mediation Program is only available to complainants who have availed themselves of the protections provided in 28 CFR part 27. To the extent the commenter suggests that the program be widely available to FBI employees generally, the Department declines to adopt this comment. The program was created, resourced, and implemented for FBI whistleblower complainants only, and was not intended to be accessible to all FBI employees.

Claims Involving a Breach of a Settlement Agreement

In the proposed rule, the Department proposed to add 28 CFR 27.8, which would authorize the OARM Director to

adjudicate claims involving a breach of a settlement agreement. Proposed § 27.8 provides that a party may file with the OARM Director a claim of a breach of a settlement agreement reached in proceedings under 28 CFR part 27. Any claim of a breach of a settlement agreement must be filed with the OARM Director ''within 30 days of the date on which the grounds for the claim of breach were known.''

One commenter suggested that there is a conflict of interest presented by proposed § 27.8, ''by reserving to the Department the right to decide whether the Department itself breached the settlement agreement.'' The commenter suggested that the provision should be modified to allow breach claims to be adjudicated in an external forum.

The Department declines to adopt this comment because other Department components, and not the FBI, adjudicate breach claims. Just as OARM has fairly decided FBI whistleblower retaliation claims, it can also fairly decide claims involving a breach of a settlement agreement.

The commenter additionally suggested that proposed § 27.8(a) be modified to include either a ''reasonable suspicion'' or ''knew/should have known'' standard, as, according to the commenter, ''those standards are more extensively construed in precedent and thus clearer in their application.''

The Department agrees with and adopts the latter comment. This final rule, which designates proposed § 27.8(a) as § 27.9(a) in the final rule, adds the words ''or should have been known'' after the word ''known'' in that paragraph.

Reference to 2303(d) MSPB Appeal Rights in the Final Rule

In the preamble to the proposed rule, the Department referenced the recent enactment of 5 U.S.C. 2303(d), which affords FBI whistleblowers the right to (1) appeal a final determination or corrective action order to the MSPB, and (2) subject to certain conditions, seek corrective action directly from the MSPB pursuant to 5 U.S.C. 1221. *See* 5 U.S.C. 2303(d)(1) and (d)(2).

Several commenters suggested that the final rule include specific reference to the MSPB appeal rights provided to FBI whistleblowers in 5 U.S.C. 2303(d). One commenter additionally suggested that the final rule add new paragraphs under 28 CFR 27.4 and 27.5 to require notice to the complainant of the right to file an Individual Right of Action appeal with the MSPB pursuant to 5 U.S.C. 2303, specify the time frames for doing so, and make clear that the complainant's filing of a request for review by the Deputy Attorney General under 28 CFR 27.5 does not affect the complainant's rights under 5 U.S.C. 2303(d).

In response, the Department agrees that 28 CFR part 27 should reference section 2303(d), which will be included in this final rule, as a new § 27.7 (which, in turn, requires changing proposed §§ 27.7 and 27.8 to §§ 27.8 and 27.9, respectively). The Department declines to adopt the suggestion that the final rule make clear that the complainant's filing of a request for review by the Deputy Attorney General does not affect the complainant's section 2303(d) rights. By citing to section 2303(d) in new § 27.7, the Department clearly informs complainants of the right to file an appeal with the MSPB.

Citation to MSPB Case Precedent as Binding

One commenter suggested that, given the recent passage of 5 U.S.C. 2303(d), the final rule should include a new provision specifying that ''all adjudications'' under 28 CFR part 27 will follow the case precedent of the MSPB and its reviewing courts. Relatedly, the commenter also suggests that, consistent with MSPB case precedent, the final rule should modify 28 CFR 27.1(a) to make clear that the whistleblower protections extend to ''perceived'' whistleblowers.

In response, the Department declines to adopt the suggestion that the Department adopt as binding the case law of the MSPB and its reviewing courts. While the Department looks to MSPB and related Federal cases as persuasive, the Deputy Attorney General has the ultimate authority to review and decide FBI whistleblower reprisal appeals under 28 CFR part 27.

Procedural Case Processing Information

One commenter suggested that the Department include a new procedural provision to clarify certain routine aspects of administrative litigations. The Department declines to adopt the suggestion, as case procedures and processing items are currently publicly available in case procedure and processing documents issued by the Office of the Deputy Attorney General and OARM and so need not be memorialized in this final rule.

Rewording ''Whistleblower''

One commenter suggests developing ''an alternate title for the term 'whistleblower'" because it ''seems to always have a negative connotation when used.''

In response, the Department declines to adopt the suggestion because the updated regulations are intended to reflect changes resulting from an assessment conducted by the Department in response to PPD–19, and the FBI WPEA of 2016, both of which use that terminology, and changing the term would lead to unnecessary confusion. Moreover, the Department does not perceive the term ''whistleblower'' as having any negative connotation.

The FBI's Prepublication Review Process

One commenter suggests that the Department add a provision to the final rule to modify the FBI's prepublication review process to allow for the disclosure of content that the commenter believes may otherwise be protected by the First Amendment's Free Speech Clause. The Department understands the suggestion to be directed at the FBI's prepublication review process in general, and not specifically directed at issues related to FBI whistleblower claims of unlawful reprisal. Because the FBI's prepublication process is outside the scope of 28 CFR part 27, the Department declines to adopt the suggested change.

Suspension of Security Clearances

One commenter suggested that the Department ''[p]rovide a regulation stopping the FBI from suspending security clearances of employees or suspending them from duty without pay until legal or administrative action is taken against them.'' The National Security Act of 1947 and PPD–19 make it unlawful for an agency (including the FBI) to take any action affecting an employee's eligibility for access to classified information in reprisal for making a protected disclosure. These protections against revocations of security clearances apply to FBI employees. The investigation and adjudication of allegations that the suspension or revocation of security clearances held by Department employees was in retaliation for making protected disclosures are governed by different laws than those governing FBI whistleblower reprisal allegations, including 50 U.S.C. 3341, PPD–19, and DOJ Instruction 1700.00.01. Security clearance suspensions are outside the scope of 28 CFR part 27, and the Department therefore declines to adopt this suggestion.

IV. Regulatory Analyses

In developing this final rule, the Department considered numerous statutes and executive orders applicable to rulemaking. The Department's analysis of the applicability of those

statutes and executive orders to this rule is summarized below.

A. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and Executive Order 14094 (Modernizing Regulatory Review)

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866, as supplemented by Executive Order 13563 and amended by Executive Order 14094. This rule makes procedural changes to the existing regulatory framework for resolving claims of whistleblower retaliation by FBI employees and applicants. The changes do not materially affect the number of claims or the time, cost, or resources required to address them. Accordingly, this rule does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866. The Office of Management and Budget has not reviewed this rule under these Orders.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–12, 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. 5 U.S.C. 601.

The Department certifies under 5 U.S.C. 605(b) that this final rule does not have a significant economic impact on a substantial number of small entities. This rule addresses the Department's internal process for addressing allegations of retaliation for protected whistleblowing by FBI employees and applicants. It has no application to small entities as defined above. This rule will perhaps have a tangential, indirect, and transitory impact on law firms and advocacy organizations representing FBI whistleblowers inasmuch as they would have to become familiar with the changes in procedure.

C. Paperwork Reduction Act

This final rule does not call for a new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–20. Specifically, this rule regulates administrative actions or investigations involving an agency against specific individuals or entities and thus falls outside the scope of the Paperwork Reduction Act. *See* 44 U.S.C. 3518(c)(1)(B)(ii).

D. Executive Order 13132 (Federalism)

A rule has federalism implications under Executive Order 13132 if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. E.O. 13132, sec. 1(a). The Department has analyzed this final rule under that order and determined that this rule does not have federalism implications.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–38, requires Federal agencies to determine whether a rule, if promulgated, will result in the expenditure by State, local, or Tribal Governments, in the aggregate, or by the private sector, of $100 million (adjusted for inflation) or more in any one year. 2 U.S.C. 1532(a). This final rule does not require or result in expenditures by any of the above-named entities. This rule addresses the Department's internal procedures related to protected disclosures.

F. Executive Order 12988 (Civil Justice Reform), Plain Language

This final rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988.

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

This final rule does not have tribal implications under Executive Order 13175 because it would 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.

H. Congressional Review Act

The reporting requirements of the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996), 5 U.S.C. 801–08, do not apply to this final rule. First, this rule relates primarily to agency management, personnel, and organization. 5 U.S.C. 804(3)(B). Second, to the extent that this rule affects non-agency parties such as applicants for employment and former employees, these parties are a small subset of the cases subject to the rule, and the rule does not substantially affect such parties' substantive rights or obligations. *Id.,* 803(3)(C). Instead, this rule makes changes primarily related to administrative processing of whistleblower retaliation cases. This action is accordingly not a ''rule'' as that term is used by the Congressional Review Act, *see* 5 U.S.C. 804(3), and the reporting requirement of 5 U.S.C. 801 does not apply. However, the Department is submitting a copy of this final rule to both houses of Congress and to the Comptroller General.

List of Subjects

28 CFR Part 0

Authority delegations (Government agencies), Government employees, National defense, Organization and functions (Government agencies), Privacy, Reporting and recordkeeping requirements, Whistleblowing.

28 CFR Part 27

Government Employees; Justice Department; Organization and functions (Government agencies); Whistleblowing.

Authority and Issuance

For the reasons stated above, the Department of Justice amends 28 CFR parts 0 and 27 as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

■ 1. The authority citation for part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

§ 0.29d [Amended]

■ 2. In § 0.29d(a), remove the words ''a violation of any law, rule, or regulation, or mismanagement'' and add, in their place, the words ''any violation of any law, rule, or regulation, or gross mismanagement.''

PART 27—WHISTLEBLOWER PROTECTION FOR FEDERAL BUREAU OF INVESTIGATION EMPLOYEES

■ 3. The authority citation for part 27 is revised to read as follows:

Authority: 5 U.S.C. 301, 3151; 28 U.S.C. 509, 510, 515–519; 5 U.S.C. 2303; President's Memorandum to the Attorney General, Delegation of Responsibilities Concerning FBI Employees Under the Civil Service Reform Act of 1978, 3 CFR p. 284 (1997); Presidential Policy Directive 19, ''Protecting Whistleblowers with Access to Classified Information'' (October 10, 2012).

■ 4. Amend § 27.1 by revising paragraph (a) and adding paragraph (c) to read as follows:

§ 27.1 Making a protected disclosure.

(a) When an employee of, or applicant for employment with, the Federal

Bureau of Investigation (FBI) (FBI employee) makes a disclosure of information to a supervisor in the direct chain of command of the employee, up to and including the Attorney General; to the Department of Justice's (Department's) Office of the Inspector General (OIG), the Department's Office of Professional Responsibility (OPR), the FBI Office of Professional Responsibility (FBI OPR), or the FBI Inspection Division (FBI–INSD) (collectively, Receiving Offices); to Congress as described in 5 U.S.C. 7211; to the Office of Special Counsel; or to an employee of any of the foregoing entities when designated by any officer, employee, office, or division named in this subsection for the purpose of receiving such disclosures, the disclosure will be a ''protected disclosure'' if the person making it reasonably believes that it evidences:

(1) Any violation of any law, rule or regulation; or

(2) Gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety.

* * * * *

(c) To be a ''protected disclosure'' under this part, the disclosure must be made to an office or official specified in paragraph (a) of this section.

§ 27.2 [Amended]

■ 5. In § 27.2, paragraph (b), remove the reference ''(xi)'' and add, in its place, the reference ''(xii)''.

■ 6. Amend § 27.4 by:

■ a. Revising paragraphs (a), (c)(1), (e)(1), (e)(3), (f), and (g); and

■ b. Adding paragraphs (e)(4), (h), (i), and (j).

The revisions and additions read as follows:

§ 27.4 Corrective action and other relief; Director, Office of Attorney Recruitment and Management.

(a) If, in connection with any investigation, the Conducting Office determines that there are reasonable grounds to believe that a reprisal has been or will be taken, the Conducting Office shall report this conclusion, together with any findings and recommendations for corrective action, to the Director, Office of Attorney Recruitment and Management (the Director). If the Conducting Office's report to the Director includes a recommendation for corrective action, the Director shall provide an opportunity for comments on the report by the FBI and the Complainant. The Director, upon receipt of the Conducting Office's report, shall proceed in accordance with paragraphs (e) and (f) of this section. A determination by the Conducting Office that there are reasonable grounds to believe that a reprisal has been or will be taken shall not be cited or referred to in any proceeding under these regulations, without the Complainant's consent.

* * * * *

(c)(1) The Complainant may present a request for corrective action directly to the Director within 60 calendar days of receipt of notification of termination of an investigation by the Conducting Office or at any time after 120 calendar days from the date the Complainant first notified an Investigative Office of an alleged reprisal if the Complainant has not been notified by the Conducting Office that it will seek corrective action. Within 5 business days of the receipt of the request, the Director shall issue an Acknowledgement Order in accordance with paragraph (f)(1) of this section.

* * * * *

(e)(1) The Director shall determine based upon all the evidence, whether a protected disclosure was a contributing factor in a personnel action taken or to be taken. Subject to paragraph (e)(2) of this section, if the Director determines that a protected disclosure was a contributing factor in a personnel action taken or to be taken, the Director shall order corrective action as the Director deems appropriate. The Director may conclude that the disclosure was a contributing factor in the personnel action based upon circumstantial evidence, such as evidence that the employee taking the personnel action knew of the disclosure and that the personnel action occurred within a period of time such that a reasonable person could conclude that the disclosure was a contributing factor in the personnel action. The determination made by the Director under this section shall be independent and impartial.

* * * * *

(3) In making the determinations required under this paragraph, the Director may hold a hearing at which the Complainant may present evidence in support of his or her claim, in accordance with such procedures as the Director may adopt. The Director is hereby authorized to compel the attendance and testimony of, or the production of documentary or other evidence from, any person employed by the Department if doing so appears reasonably calculated to lead to the discovery of admissible evidence, is not otherwise prohibited by law or regulation, and is not unduly burdensome. The Director may prohibit a party from adducing or relying on evidence from a person whom the opposing party does not have an opportunity to examine, or the Director may give less weight to such evidence. In excluding such evidence, the Director may consider certain factors, including, but not limited to: the probative value of the evidence; whether the evidence is supported by sufficient guarantees of trustworthiness after considering the totality of the circumstances under which it was made and any corroborating evidence; and whether the evidence is duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive. Any privilege available in judicial and administrative proceedings relating to the disclosure of documents or the giving of testimony shall be available before the Director. All assertions of such privileges shall be decided by the Director. The Director may, upon request, certify a ruling on an assertion of privilege for review by the Deputy Attorney General.

(4) Subject to paragraph (f) of this section, the Director may establish such procedures as the Director deems reasonably necessary to carry out the functions assigned under this paragraph.

(f)(1) Within 5 business days of receipt by the Director under paragraph (a) of this section of a report from a Conducting Office, or a request for corrective action from a Complainant under paragraph (c)(1) of this section, the Director shall issue an Acknowledgement Order that:

(i) Acknowledges receipt of the report or request;

(ii) Informs the parties of the relevant case processing procedures and timelines, including the manner of designation of a representative, the time periods for and methods of discovery, the process for resolution of discovery disputes, and the form and method of filing of pleadings;

(iii) Informs the parties of the jurisdictional requirements for full adjudication of the request; and

(iv) Informs the parties of their respective burdens of proof.

(2) In cases where the Director determines that there is a question about the Director's jurisdiction to review a request from the Complainant, the Director shall, simultaneously with the issuance of the Acknowledgement Order, issue a Show-Cause Order explaining the grounds for such determination and directing that the Complainant, within 15 calendar days of receipt of such order, submit a written statement, accompanied by evidence, to explain why the request should not be dismissed for lack of jurisdiction. The Complainant's written

statement must provide the following information as necessary to address the jurisdictional question or as otherwise directed:

(i) The alleged protected disclosure or disclosures;

(ii) The date on which the Complainant made any such disclosure;

(iii) The name and title of any individual or office to whom the Complainant made any such disclosure;

(iv) The basis for the Complainant's reasonable belief that any such disclosure evidenced any violation of law, rule, or regulation; gross mismanagement; a gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety;

(v) Any action the FBI allegedly took or failed to take, or threatened to take or fail to take, against the Complainant because of any such disclosure, the name and title of all officials responsible for each action, and the date of each action;

(vi) The basis for the Complainant's belief that any official responsible for an action knew of any protected disclosure, and the date on which the official learned of the disclosure;

(vii) The relief sought; and

(viii) The date the reprisal complaint was filed with the Investigative Office and the date on which the Conducting Office notified the Complainant that it was terminating its investigation into the complaint, or if the Complainant has not received such notice, evidence that 120 days have passed since the Complainant filed a complaint of reprisal with the Investigative Office.

(3) The FBI shall file a reply to the Complainant's response to the Show-Cause Order within 20 calendar days of receipt of such reply.

(i) The reply shall address issues identified by the Director in the Show-Cause Order and matters raised in the Complainant's response to that order under paragraph (f)(2) of this section, and shall include: a statement identifying any FBI actions taken against the Complainant and the reasons for taking such actions; designation of and signature by the FBI legal representative; and any other documents or information requested by the Director.

(ii) The reply may also include any and all documents contained in the FBI record of the action or actions.

(4) After receipt of the FBI's response, the record on the jurisdictional issue will close, absent a request from either party establishing exigent circumstances requiring the need for the presentation of additional evidence or arguments.

(g) If the Director orders corrective action, such corrective action shall, as appropriate, include: placing the Complainant, as nearly as possible, in the position the Complainant would have been in had the reprisal not taken place; reimbursement for attorney's fees, reasonable costs, medical costs incurred, and travel expenses; back pay and related benefits; compensatory damages to the extent authorized by law; and any reasonable and foreseeable consequential damages.

(h) Whenever the Director determines that there has been a reprisal prohibited by § 27.2 of this part, the Director, in addition to ordering any corrective action as authorized by § 27.4(g), shall forward to FBI OPR, FBI–INSD, and the Director of the FBI, a copy of the Director's written opinion finding that there has been a prohibited reprisal. FBI OPR shall make an independent determination of whether disciplinary action is warranted.

(i) If the Director determines that there has not been any reprisal prohibited by § 27.2, the Director shall report this finding in writing to the Complainant, the FBI, and the Conducting Office.

(j) The Director will not cite or rely upon any unpublished FBI whistleblower decision issued by the Director or Deputy Attorney General in rendering any decision under § 27.4.

■ 7. Revise § 27.5 to read as follows:

§ 27.5 Review.

(a) Within 30 calendar days of a finding of a lack of jurisdiction, a final determination on the merits, or corrective action ordered by the Director, the Complainant or the FBI may request review by the Deputy Attorney General of that determination or order. The Deputy Attorney General shall set aside or modify the Director's actions, findings, or conclusions found to be arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law; obtained without procedures required by law, rule, or regulation having been followed; or unsupported by substantial evidence. The Deputy Attorney General has full discretion to review and modify corrective action ordered by the Director, provided, however that if the Deputy Attorney General upholds a finding that there has been a reprisal, then the Deputy Attorney General shall order appropriate corrective action.

(b) The parties may not file an interlocutory appeal to the Deputy Attorney General from a procedural ruling made by the Director during proceedings pursuant to § 27.4 of this part. The Deputy Attorney General has full discretion to review such rulings by the Director during the course of reviewing an appeal of the Director's finding of a lack of jurisdiction, final determination, or corrective action order brought under paragraph (a) of this section.

(c) In carrying out the functions set forth in this section, the Deputy Attorney General may issue written directives or orders to the parties as necessary to ensure the efficient and fair administration and management of the review process.

■ 8. Add § 27.7 to read as follows:

§ 27.7 Right to appeal to or seek corrective relief from the U.S. Merit Systems Protection Board.

An FBI whistleblower may appeal to, or seek corrective relief from, the U.S. Merit Systems Protection Board in accordance with the provisions of 5 U.S.C. 2303(d).

■ 9. Add § 27.8 to read as follows:

§ 27.8 Alternative dispute resolution.

(a) At any stage in the process set forth in §§ 27.3 through 27.5 of this part, the Complainant may request Alternative Dispute Resolution (ADR) through the Department of Justice Mediator Corps (DOJMC) Program. The Complainant may elect to participate in ADR by notifying in writing the office before which the matter is then pending.

(b) If the Complainant elects mediation, the FBI, represented by the Office of General Counsel, will participate.

(c) When the Complainant requests to engage in ADR, the process set forth in §§ 27.3 through 27.5, as applicable, including all time periods specified therein, will be stayed for an initial period of 90 days, beginning on the date of transmittal of the matter to the DOJMC Program office. Upon joint request by the parties to the office before which the matter is stayed, the period of the stay may be extended up to an additional 45 days. Further requests for extension of the stay may be granted only by the Director, regardless of the office before which the matter is pending, upon a joint request showing good cause. The stay otherwise will be lifted if the DOJMC Program notifies the office before which the matter is stayed that the Complainant no longer wishes to engage in mediation, or that the parties are unable to reach agreement on resolution of the complaint and that continued efforts at mediation would not be productive.

■ 10. Add § 27.9 to read as follows:

§ 27.9 Authority of the Director to review and decide claims of a breach of a settlement agreement.

(a) Any party to a settlement agreement reached in proceedings and in a forum under this part may file a claim of a breach of that settlement agreement with the Director within 30 days of the date on which the grounds for the claim of breach were known or should have been known.

(b) The Director shall adjudicate any timely claim of a breach of a settlement agreement. The Director shall exercise the authority granted under § 27.4(e)(4) to ensure the efficient administration and management of the adjudication of the breach claim, pursuant to any procedures the Director deems reasonably necessary to carry out the functions assigned under this paragraph.

(c) A party may request, within 30 calendar days of a decision on a claim of a breach of a settlement agreement by the Director, review of that decision by the Deputy Attorney General.

Dated: January 25, 2024.

Merrick B. Garland,

Attorney General.

[FR Doc. 2024–01934 Filed 2–1–24; 8:45 am]

BILLING CODE 4410–AR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2023–0652]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Jupiter, FL

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily modifying the operating schedule that governs the Indiantown Road Bridge across the Atlantic Intracoastal Waterway (AICW), mile 1006.2, at Jupiter, Florida. This action is necessary to alleviate vehicle traffic congestion on the Indiantown Road Bridge caused by the replacement of another nearby bridge. Once construction of the nearby bridge is complete, the Indiantown Road Drawbridge will return to normal scheduled operations.

DATES: This temporary final rule is effective from 12:01 a.m. on February 5, 2024, through 11:59 p.m. on August 31, 2025.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type the docket number USCG–2023–0652 in the ''SEARCH'' box and click ''SEARCH''. In the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, call or email Mr. Leonard Newsom, Seventh District Bridge Branch, Coast Guard; telephone (305) 415–6946, email *Leonard.D.Newsom@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of proposed rulemaking (advance, supplemental)
§ Section
U.S.C. United States Code
FL Florida
AICW Atlantic Intracoastal Waterway
FDOT Florida Department of Transportation

II. Background Information and Regulatory History

On October 20, 2023, the Coast Guard published a notice of proposed rulemaking entitled ''Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, at Jupiter, FL'' in the **Federal Register** (88 FR 72415). There we stated why we issued the NPRM and invited comments on our proposed regulatory action related to this regulatory change. During the NPRM comment period that ended November 20, 2023, no comments were received.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 499. The Indiantown Road Bridge across the AICW, mile 1006.2, at Jupiter, Florida. The Indiantown Road Bridge is a double-leaf bascule bridge with 35 feet of vertical clearance in the closed position. The operating schedule requires the bridge to open each hour and half-hour as needed per 33 CFR 117.261(q).

The bridge owner, Florida Department of Transportation, has requested this change during the replacement of an adjacent bridge. The closing of the adjacent bridge has resulted in significant increase in vehicle traffic congestion of the area. The only alternate route for land traffic to access the mainland is via the Donald Ross Bridge approximately 4.5 miles south of the Indiantown Road Bridge. This rule will reduce the number of openings which will subsequently allow the local traffic to flow with less obstructions and delay.

IV. Discussion of Comments, Changes, and the Temporary Final Rule

The Coast Guard provided a comment period of 30 days, and no comments were received. The current regulation provides for the bridge to open twice an hour. This temporary final rule allows for the bridge to remain closed to navigation during designated times and all other times open twice an hour. Vessels that can pass beneath the bridge without an opening may do so at any time.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the ability that vessels able to transit the bridge while in the closed position may do so at any time.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 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 received zero comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant

economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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

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

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Chapter 3, Table3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and DHS Delegation No. 00170.1, Revision No. 01.3.

■ 2. Amend § 117.261 by:
■ a. Adding paragraph (p); and
■ b. Staying paragraph (q).
The addition reads as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(p) *Indiantown Road Bridge, mile 1006.2, at Jupiter.* The draw shall open on the hour and half hour except that the draw need not open daily from 7 to 9 a.m. and 4 to 6 p.m.

* * * * *

Dated: January 27, 2024.

Douglas M. Schofield,

Rear Admiral, U.S. Coast Guard, Commander, Coast Guard Seventh District.

[FR Doc. 2024–02084 Filed 2–1–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–0124]

Safety Zone; Military Ocean Terminal Concord Safety Zone, Suisun Bay, Concord, CA

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone in the navigable waters of Suisun Bay, off Concord, CA, in support of explosive handling operations at Military Ocean Terminal Concord, CA (MOTCO), on February 2, 2024, through February 9, 2024. This safety zone is necessary to protect personnel, vessels, and the marine environment from potential explosion within the explosive arc. The safety zone is open to all persons and vessels for transitory use, but vessel operators desiring to anchor or otherwise loiter within the safety zone must obtain permission of the Captain of the Port (COTP) San Francisco or a designated representative.

DATES: The regulations in 33 CFR 165.1198 will be enforced from 12:01 a.m. on February 2, 2024, until 11:59 p.m. on February 9, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LT William Harris, U.S. Coast Guard Sector San Francisco, Waterways Management Division, at telephone 415–399–7443, email *SFWaterways@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in 33 CFR 165.1198 for the Military Ocean Terminal Concord, CA (MOTCO), regulated area from 12:01 a.m. on February 2, 2024, until 11:59 p.m. on February 9, 2024, or as announced via marine information bulletin. This safety zone is necessary to protect personnel,

vessels, and the marine environment from potential explosion within the explosive arc. The regulation for this safety zone, § 165.1198, specifies the location of the safety zone which encompasses the navigable waters in the area between 500 yards of MOTCO Pier in position 38°03′30″ N, 122°01′14″ W and 3,000 yards of the pier. During the enforcement period, as reflected in § 165.1198(d), if you are the operator of a vessel in the regulated area you must comply with the instruction of the COTP or the designated on-scene patrol personnel. Vessel operators desiring to anchor or otherwise loiter within the safety zone must contact Sector San Francisco Vessel Traffic Service at 415–556–2760 or VHF Channel 14 to obtain permission.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via marine information broadcasts.

Dated: January 29, 2024.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. 2024–02127 Filed 2–1–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2021–0367; FRL–11573–02–R4]

Air Plan Approval; Alabama; Birmingham Limited Maintenance Plan for the 2006 24-Hour $PM_{2.5}$ NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing the approval of a State Implementation Plan (SIP) revision submitted by the State of Alabama, through the Alabama Department of Environmental Management (ADEM), via a letter dated February 2, 2021. The SIP revision includes the 2006 24-hour fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS) Limited Maintenance Plan (LMP) for the Birmingham, Alabama maintenance area (Birmingham Area or Area). The Birmingham 2006 24-hour $PM_{2.5}$ maintenance area is comprised of Jefferson County, Shelby County, and a portion of Walker County. EPA is approving the Birmingham Area LMP because it provides for the maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS within the Birmingham Area through the end of the second 10-year portion of the maintenance period. The effect of this action would be to make certain commitments related to maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS in Birmingham federally enforceable as part of the Alabama SIP. EPA is also notifying the public of the status of EPA's adequacy determination, consistent with the requirements in the transportation conformity rule, for this LMP.

DATES: This rule is effective March 4, 2024.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2021–0367. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dianna Myers, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9207. Ms. Myers can also be reached via electronic mail at *myers.dianna@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Clean Air Act (CAA or Act), EPA is approving the Birmingham LMP for the 2006 24-hour $PM_{2.5}$ NAAQS, adopted by ADEM on February 2, 2021, and submitted by ADEM as a revision to the Alabama SIP under a cover letter with the same date.[1] On November 13, 2009, EPA promulgated designations for the 2006 24-hour $PM_{2.5}$ NAAQS, designating the Birmingham Area, which includes Jefferson County, Shelby County, and a portion of Walker County, as nonattainment for the 2006 24-hour $PM_{2.5}$ NAAQS based upon air quality data for calendar years 2006 through 2008. *See* 74 FR 58688. Subsequently, on January 25, 2013, EPA approved the Birmingham Area's maintenance plan and the State's request to redesignate the Birmingham Area to attainment for the 2006 24-hour $PM_{2.5}$ NAAQS. *See* 78 FR 5306.

The Birmingham LMP for the 2006 24-hour $PM_{2.5}$ NAAQS is designed to maintain the 2006 24-hour $PM_{2.5}$ NAAQS within Birmingham through the end of the second 10-year portion of the maintenance period beyond redesignation or 2034. EPA is approving the plan because it meets all applicable requirements under CAA sections 110 and 175A. As a general matter, the Birmingham LMP for the 2006 24-hour $PM_{2.5}$ NAAQS relies on the same control measures and similar contingency provisions to maintain the 2006 24-hour $PM_{2.5}$ NAAQS during the second 10-year portion of the maintenance period as the maintenance plan submitted by ADEM for the first 10-year period.

In a notice of proposed rulemaking (NPRM) published on December 13, 2023 (88 FR 86303), EPA proposed to approve the Birmingham LMP because the State made a showing, consistent with EPA's LMP guidance, that the Birmingham Area's $PM_{2.5}$ concentrations are well below the 2006 24-hour $PM_{2.5}$ NAAQS, have been historically stable, and that it has met all other maintenance plan requirements. The details of Alabama's submission and the rationale for EPA's action are explained further in the December 13, 2023, NPRM. Comments on the December 13, 2023, NPRM were due on or before January 12, 2024. No comments were received on the NPRM, adverse or otherwise.

II. Final Action

In accordance with sections 110(k) and 175A of the CAA, and for the reasons set forth above and in the NPRM, EPA is finalizing its approval of the Birmingham Area LMP for the 2006 24-hour $PM_{2.5}$ NAAQS, submitted by ADEM on February 2, 2021, as a revision to the Alabama SIP. EPA is finalizing the approval of the Birmingham Area LMP because it

[1] EPA notes the Agency received the submittal on February 17, 2021.

includes an acceptable update of the various elements of the 2006 24-hour $PM_{2.5}$ NAAQS maintenance plan approved by EPA for the first 10-year period (including emissions inventory, assurance of adequate monitoring and verification of continued attainment, and contingency provisions), and retains the relevant provisions of the SIP.

EPA also finds that the Birmingham Area qualifies for the LMP option and adequately demonstrates maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS through documentation of monitoring data showing maximum 24-hour $PM_{2.5}$ levels well below the NAAQS (including, as explained the NPRM, average design values below the critical design values), the historically stable design values, and the continuation of existing control measures. EPA finds the Birmingham Area's 2006 24-hour $PM_{2.5}$ LMP to be sufficient to provide for maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS in the Birmingham Area over the second 10-year maintenance period, through 2034, and thereby satisfy the requirements for such a plan under CAA section 175A(b).

EPA is approving this second 10-year LMP and notifying the public that EPA finds the LMP adequate for transportation conformity purposes because it meets the adequacy criteria in 40 CFR 93.118(e)(4). After 2024, the motor vehicle emissions in the Birmingham Area may be treated as essentially not constraining for the second 10-year maintenance period because EPA concludes that it is unreasonable to expect that the area will experience enough motor vehicle emissions growth that a violation of the $PM_{2.5}$ NAAQS would result. Therefore, all actions for transportation plans and transportation improvement programs that would require a transportation conformity determination for the Birmingham 2006 24-hour $PM_{2.5}$ maintenance area under EPA's transportation conformity rule provisions are considered to have already satisfied the regional emissions analysis and ''budget test'' requirements in 40 CFR 93.118. *See* 40 CFR 93.109(e).

III. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

ADEM did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral to positive impact on the air quality of the affected area. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

This action is subject to the Congressional Review Act, 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).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 2, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: January 29, 2024.

Jeaneanne Gettle,

Acting Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

Authority: 42 U.S.C. 7401 *et seq.*

Subpart B—Alabama

■ 2. In § 52.50(e), amend the table by adding an entry for ''2006 24-hour $PM_{2.5}$ Second Maintenance Plan (Limited Maintenance Plan) for the Birmingham Area'' at the end of the table to read as follows:

§ 52.50 Identification of plan.

* * * * *

(e) * * *

EPA APPROVED ALABAMA NON-REGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approval date	Explanation
*	*	*	*	*
2006 24-hour $PM_{2.5}$ Second Maintenance Plan (Limited Maintenance Plan) for the Birmingham Area.	Birmingham $PM_{2.5}$ Maintenance Area.	2/2/2021	2/2/2024, [Insert citation of publication].	.....

[FR Doc. 2024–02078 Filed 2–1–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0868; FRL–11673–01–OCSPP]

Saflufenacil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of saflufenacil in or on corn, field, forage; corn, field, stover; and corn, field, milled byproducts; and amends the existing commodity definition for Crop Group 16 to Crop Group 16–22. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 2, 2024. Objections and requests for hearings must be received on or before April 2, 2024, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0868, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2022–0868 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before April 2, 2024. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2022–0868, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets.*

Additional instructions on commenting or visiting the docket,

along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 5, 2023 (88 FR 42935) (FRL–10579–05–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F9019) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.649(a)(1) be amended by establishing tolerances for residues of the herbicide saflufenacil, including its metabolites and degradates, in or on Corn, field, forage at 0.3 parts per million (ppm), Corn, field, milled byproducts at 0.125 ppm, and Corn, field, stover at 5.0 ppm. The petition also requested to amend the existing commodity definition in 40 CFR 180.649(a)(1) for residues of the herbicide saflufenacil, including its metabolites and degradates, in or on ''Grain, cereal, forage, fodder and straw group 16 (except barley and wheat straw)'' to ''Grain, cereal, forage, hay, stover, and straw group 16–22 (except field corn forage, field corn stover, barley straw, wheat straw, and chia straw)'' unchanged at 0.1 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA has made modifications to the proposed tolerance values and commodity definitions. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking in 2015 for saflufenacil in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to saflufenacil and established tolerances for residues of that chemical. EPA is incorporating previously published sections from that rulemaking as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the toxicological profile for saflufenacil, see Unit III.A. of the saflufenacil tolerance rulemaking published in the **Federal Register** of November 25, 2015 (80 FR 73663) (FRL–9936–71).

Toxicological points of departure/Levels of concern. A summary of the toxicological points of departure and levels of concern for saflufenacil used for human health risk assessment is discussed in Unit III.B. of the November 25, 2015, rulemaking.

Exposure assessment. Much of the exposure assessment remains unchanged from the November 2015 rulemaking, although updates have occurred to accommodate the exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C of the November 25, 2015, rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the petitioned-for tolerances for saflufenacil. Acute and chronic dietary exposure assessments were performed for saflufenacil that incorporated tolerance-level residues, 100% crop treated (CT) assumptions, and default processing factors. These assessments were revised to reflect the updated Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID), Version 4.02, which incorporates 2005–2010 consumption data from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute and chronic estimated drinking water concentrations (EDWCs) of 133 parts per billion (ppb) and 120 ppb, respectively, are unchanged from the November 25, 2015, rulemaking and were directly incorporated into the dietary assessments. A cancer dietary assessment was not conducted as saflufenacil is classified as ''not likely'' to be a human carcinogen. Saflufenacil is not registered for any specific use patterns that would result in residential exposure. Therefore, a quantitative residential exposure assessment was not conducted.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' EPA has not found saflufenacil to share a common mechanism of toxicity with any other substances, and saflufenacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that saflufenacil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the

reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the November 25, 2015, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and Determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and the chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

Acute dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the acute population adjusted dose (aPAD); they are <1% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure. Chronic dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD); they are 26% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. There is no short- or intermediate-term residential exposure expected since there are no proposed or previously registered residential uses of saflufenacil. Therefore, the acute and chronic aggregate risks consist only of the dietary risks from food and water only, and as stated above, are below the Agency's level of concern. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, saflufenacil is not expected to pose a cancer risk to humans.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to saflufenacil residues, including its metabolites and degradates. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the document titled ''Saflufenacil. Human Health Risk Assessment for Proposed New and Amended Uses on Field Corn Commodities, Post-Harvest and Fallow'' in docket ID number EPA–HQ–OPP–2022–0868.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography with tandem mass spectroscopy detection (HPLC–MS/MS) Method D0603/04) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex has not established MRLs for saflufenacil for feed items of raw agricultural commodities. Therefore, harmonization of MRLs and U.S. tolerances is not an issue at this time.

C. Revisions to Petitioned-For Tolerances

EPA is revising the tolerance level proposed for corn, field, forage from 0.3 ppm to 0.4 ppm based on field trial residues values and the combined residue calculation. The tolerance level proposed for corn, field, stover is also being revised from 5.0 ppm to 5 ppm based on the Organization for Economic Co-operation and Development (OECD) rounding class practice. EPA is also revising the tolerance level proposed for corn, field, milled byproducts from 0.125 ppm to 0.2 ppm to adjust for degree of exaggeration and the OECD rounding class. Also, EPA is revising the proposed commodity definition ''Grain, cereal, forage, hay, stover, and straw group 16–22 (except field corn forage, field corn stover, barley straw, wheat straw, and chia straw)'' to the following definitions to align better with the Agency's current preferred commodity vocabulary: ''Grain, cereal, forage, hay, stover, and straw, group 16–22, forage, except corn, field, forage''; ''Grain, cereal, forage, hay, stover, and straw, group 16–22, hay''; ''Grain, cereal, forage, hay, stover, and straw, group 16–22, stover, except corn, field, stover''; and ''Grain, cereal, forage, hay, stover, and straw, group 16–22, straw, except barley, chia, and wheat, straw.''

V. Conclusion

Therefore, tolerances are established for residues of saflufenacil, including its metabolites and degradates, in or on Corn, field, forage at 0.4 ppm; Corn, field, milled byproducts at 0.2 ppm; Corn, field, stover at 5 ppm; Grain, cereal, forage, hay, stover, and straw, group 16–22, forage, except corn, field, forage at 0.1 ppm; Grain, cereal, forage, hay, stover, and straw, group 16–22, hay at 0.1 ppm; Grain, cereal, forage, hay, stover, and straw, group 16–22, stover, except corn, field, stover at 0.1 ppm; and Grain, cereal, forage, hay, stover, and straw, group 16–22, straw, except barley, chia, and wheat, straw at 0.1 ppm. In addition, EPA is removing the established tolerance in or on Grain, cereal, forage, fodder and straw group 16 (except barley and wheat straw) at 0.1 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the

relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: January 30, 2024.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

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

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

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

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

■ 2. In § 180.649, amend the table in paragraph (a)(1) by:

■ a. Adding in alphabetical order the entries ''Corn, field, forage''; ''Corn, field, milled byproducts''; and ''Corn, field, stover''.

■ b. Removing the entry for ''Grain, cereal, forage, fodder and straw group 16 (except barley and wheat straw)''.

■ c. Adding in alphabetical order the entries ''Grain, cereal, forage, hay, stover, and straw, group 16–22, forage, except corn, field, forage''; ''Grain, cereal, forage, hay, stover, and straw, group 16–22, hay''; ''Grain, cereal, forage, hay, stover, and straw, group 16–22, stover, except corn, field, stover''; and ''Grain, cereal, forage, hay, stover, and straw, group 16–22, straw, except barley, chia, and wheat, straw''.

The additions read as follows:

§ 180.649 Saflufenacil; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
* * * * * * *	
Corn, field, forage	0.4
Corn, field, milled byproducts	0.2
Corn, field, stover	5
* * * * * * *	
Grain, cereal, forage, hay, stover, and straw, group 16–22, forage, except corn, field, forage	0.1
Grain, cereal, forage, hay, stover, and straw, group 16–22, hay	0.1
Grain, cereal, forage, hay, stover, and straw, group 16–22, stover, except corn, field, stover	0.1
Grain, cereal, forage, hay, stover, and straw, group 16–22, straw, except barley, chia, and wheat, straw	0.1
* * * * * * *	

* * * * *

[FR Doc. 2024–02092 Filed 2–1–24; 8:45 am]

BILLING CODE 6560–50–P

LEGAL SERVICES CORPORATION

45 CFR Part 1611

Income Level for Individuals Eligible for Assistance; Correction

AGENCY: Legal Services Corporation.

ACTION: Final rule; correcting amendment.

SUMMARY: The Legal Services Corporation (LSC) is correcting a final rule that appeared in the **Federal Register** on January 24, 2024. That document contained a chart listing an incorrect income level for 125% of the Federal Poverty Guidelines for a household of two in the 48 contiguous states and DC This document corrects the income representing 125% of the Federal Poverty Guidelines for a household of two in the 48 contiguous States and DC.

DATES: This correcting amendment is effective February 2, 2024 and is applicable beginning January 24, 2024.

FOR FURTHER INFORMATION CONTACT: Stefanie Davis, Deputy General Counsel and Ethics Officer, Legal Services Corporation, 3333 K St. NW, Washington, DC 20007; (202) 295–1563; *sdavis@lsc.gov.*

SUPPLEMENTARY INFORMATION: LSC is correcting appendix A to part 1611 due to an error in revising it in a final rule that published in the **Federal Register** on January 24, 2024, at 89 FR 4562. The rule was effective on date of publication. The table entitled ''Legal Services Corporation 2024 Income Guidelines'' contained an error in one of its entries. This document corrects that error.

List of Subjects in 45 CFR Part 1611

Grant programs—law, Legal services.

Accordingly, LSC amends 45 CFR part 1611 by making the following correcting amendment:

PART 1611—ELIGIBILITY

■ 1. The authority citation for part 1611 continues to read as follows:

Authority: 42 U.S.C. 2996g(e).

■ 2. In appendix A to part 1611, in the table entitled ''Legal Services

Corporation 2024 Income Guidelines,'' entry 2 is revised to read as follows:

Appendix A to Part 1611—Income Level for Individuals Eligible for Assistance

LEGAL SERVICES CORPORATION 2024 INCOME GUIDELINES *

Size of household	48 Contiguous States and the District of Columbia	Alaska	Hawaii
* * * *	*	*	*
2	25,550	31,925	29,375
* * * *	*	*	*

* The figures in this table represent 125% of the Federal Poverty Guidelines by household size as determined by HHS.

* * * * *

Dated: January 29, 2024.

Stefanie Davis,

Deputy General Counsel and Ethics Officer, Legal Services Corporation.

[FR Doc. 2024–02017 Filed 2–1–24; 8:45 am]

BILLING CODE 7050–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 11

[Docket No. FWS–HQ–LE–2023–0257; FF09L00200–FX–LE12200900000]

RIN 1018–BH16

Civil Penalties; 2024 Inflation Adjustments for Civil Monetary Penalties

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service or we) is issuing this final rule, in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Inflation Adjustment Act) and Office of Management and Budget (OMB) guidance, to adjust for inflation the statutory civil monetary penalties that may be assessed for violations of Service-administered statutes and their implementing regulations. We are required to adjust civil monetary penalties annually for inflation according to a formula specified in the Inflation Adjustment Act. This rule replaces the previously issued amounts with the updated amounts after using the 2024 inflation adjustment multiplier provided in the OMB guidance.

DATES: This rule is effective February 2, 2024.

ADDRESSES: This rule may be found on the internet at *https://www.regulations.gov* in Docket No. FWS–HQ–LE–2023–0257.

FOR FURTHER INFORMATION CONTACT: Douglas Ault, Special Agent in Charge, Headquarters Investigations Unit, U.S. Fish and Wildlife Service, Office of Law Enforcement, (703) 358–2290. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Background

The regulations in title 50 of the Code of Federal Regulations at 50 CFR part 11 provide uniform rules and procedures for the assessment of civil penalties resulting from violations of certain laws and regulations enforced by the Service.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (sec. 701 of Pub. L. 114–74) (Inflation Adjustment Act) required Federal agencies to adjust the level of civil monetary penalties with an initial ''catch up'' adjustment through rulemaking and then make subsequent annual adjustments for inflation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes.

Under section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Inflation Adjustment Act, each Federal agency is required to issue regulations adjusting for inflation the statutory civil monetary penalties (civil penalties) that can be imposed under the laws administered by that agency. The Inflation Adjustment Act provided that the initial ''catch up adjustment'' take effect no later than August 1, 2016, followed by subsequent adjustments to be made no later than January 15 every year thereafter. This final rule adjusts the civil penalty amounts that may be imposed pursuant to each statutory provision beginning on the date specified above in **DATES**.

On June 28, 2016, the Service published in the **Federal Register** an interim rule that revised 50 CFR part 11 (81 FR 41862) to carry out the Inflation Adjustment Act. The Service subsequently published a final rule to that interim rule on December 23, 2016 (81 FR 94274). The Service has published final rules every year thereafter, further adjusting the civil penalty amounts in 50 CFR 11.33 per OMB guidance:

- 82 FR 6307, January 19, 2017;
- 83 FR 5950, February 12, 2018;
- 84 FR 15525, April 16, 2019;
- 85 FR 10310, February 24, 2020;
- 86 FR 15427, March 23, 2021;
- 87 FR 13948, March 11, 2022; and
- 88 FR 5796, January 30, 2023.

This final rule adjusts the civil monetary penalty amounts that were listed in the 2023 final rule and subsequently codified at 50 CFR 11.33 by using the 2024 inflation multiplier provided to all Federal agencies by OMB (see below).

OMB issued a memorandum, M–24–07, entitled ''Implementation of Penalty Inflation Adjustments for 2024, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,'' which provides the cost-of-living adjustment multiplier for 2024: 1.03241. Therefore, we multiplied each penalty in the table in 50 CFR 11.33 by 1.03241 to obtain the 2024 annual adjustment. The new amounts are reflected in the table in the rule portion of this document and replace the current amounts in 50 CFR 11.33.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866, 13563, and 14094)

Executive Order (E.O.) 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). E.O. 12866, as reaffirmed by E.O. 13563 and E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

In addition, in this final rule, we affirm the required determinations that we made in the June 28, 2016, interim rule (81 FR 41862); for descriptions of our actions to ensure compliance with the following statutes and Executive orders, see that rule:

- National Environmental Policy Act (42 U.S.C. 4321 *et seq.*);
- Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2));
- Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*);
- Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*); and
- Executive Orders 12630, 12988, 13132, 13175, and 13211.

Administrative Procedure Act

As stated above, under section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Inflation Adjustment Act, Public Law 114–74, 129 Stat. 584 (2015), each Federal agency is required to issue regulations adjusting for inflation the statutory civil monetary penalties that can be imposed under the laws administered by that agency. The Inflation Adjustment Act provided for an initial ''catch up adjustment'' to take effect no later than August 1, 2016, followed by subsequent adjustments to be made no later than January 15 every year thereafter. This final rule adjusts the civil penalty amounts that may be imposed pursuant to each statutory provision beginning on the effective date of this rule. To comply with the Inflation Adjustment Act, we are issuing these regulations as a final rule.

Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for prior public comment. The Service finds that providing for public comment before issuing this rule is unnecessary as this rulemaking is a nondiscretionary action. The Service is required to publish this rule to update the civil penalty amounts by the specified formula described above. The Service has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Since this update to the January 30, 2023, final rule (88 FR 5796) is merely ministerial, we find that pre-publication notice and public comment with respect to the revisions set forth in this rule is unnecessary. We also posit that we have good cause under 5 U.S.C. 553(d) to make this rule effective upon publication to meet the statutory deadline imposed by the Inflation Adjustment Act.

List of Subjects in 50 CFR Part 11

Administrative practice and procedure, Exports, Fish, Imports, Penalties, Plants, Transportation, Wildlife.

Regulation Promulgation

For the reasons described above, we amend part 11, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below.

PART 11—CIVIL PROCEDURES

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 16 U.S.C. 470aa–470mm, 470aaa–470aaa–11, 668–668d, 1361–1384, 1401–1407, 1531–1544, 3371–3378, 4201–4245, 4901–4916, 5201–5207, 5301–5306; 18 U.S.C. 42–43; 25 U.S.C. 3001–3013; and Sec. 107, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

■ 2. Revise the table in § 11.33 to read as follows:

§ 11.33 Adjustments to penalties.

* * * * *

Law	Citation	Type of violation	Maximum civil monetary penalty
(a) African Elephant Conservation Act	16 U.S.C. 4224(b)	Any violation	$12,799
(b) Bald and Golden Eagle Protection Act	16 U.S.C. 668(b)	Any violation	16,170
(c) Endangered Species Act of 1973	16 U.S.C. 1540(a)(1)	(1) Knowing violation of section 1538	63,991
		(2) Other knowing violation	30,715
		(3) Any other violation	1,617
(d) Lacey Act Amendments of 1981	16 U.S.C. 3373(a)	(1) Violations referred to in 16 U.S.C. 3373(a)(1)	32,341
		(2) Violations referred to in 16 U.S.C. 3373(a)(2)	808
(e) Marine Mammal Protection Act of 1972	16 U.S.C. 1375	Any violation	32,341
(f) Recreational Hunting Safety Act of 1994	16 U.S.C. 5202(b)	(1) Violation involving use of force or violence or threatened use of force or violence.	20,579
		(2) Any other violation	10,289
(g) Rhinoceros and Tiger Conservation Act of 1998	16 U.S.C. 5305a(b)(2)	Any violation	22,512
(h) Wild Bird Conservation Act	16 U.S.C. 4912(a)(1)	(1) Violation of section 4910(a)(1), section 4910(a)(2), or any permit issued under section 4911.	54,243
		(2) Violation of section 4910(a)(3)	26,035
		(3) Any other violation	1,086

Shannon Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2024–02111 Filed 2–1–24; 8:45 am]

BILLING CODE 4333–15–P

Proposed Rules

Federal Register
Vol. 89, No. 23
Friday, February 2, 2024

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–2024–0045; Project Identifier MCAI–2023–01088–A]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2023–12–17, which applies to Pilatus Aircraft Ltd. (Pilatus) Model PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes. AD 2023–12–17 requires revising the airworthiness limitation section (ALS) of the existing aircraft maintenance manual (AMM) or Instructions for Continued Airworthiness (ICA) for your airplane by introducing new and more restrictive instructions and maintenance tasks as specified in the component limitations section, which includes repetitive inspections for cracks in the lower main spar connection of the horizontal stabilizer. Since the FAA issued AD 2023–12–17, the FAA has determined that new or more restrictive airworthiness limitations are necessary. This proposed AD would require revising the ALS of your existing AMM or ICA and your existing approved maintenance or inspection program, as applicable, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by March 18, 2024.

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

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0045; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI) any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material identified in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329–4059; email: *doug.rudolph@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–0045; Project Identifier MCAI–2023–01088–A'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Doug Rudolph, 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 2023–12–17, Amendment 39–22475 (88 FR 42604, July 3, 2023) (AD 2023–12–17), for Pilatus Model PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes. AD 2023–12–17 was prompted by MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2022–0103, dated June 9, 2022 (EASA AD 2022–0103) to correct an unsafe condition for Pilatus Model PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes identified as cracks in the lower main spar connection of the horizontal stabilizer and the failure of certain parts.

AD 2023–12–17 requires incorporating new revisions to the ALS

of the existing AMM or ICA for your airplane to establish new or more restrictive airworthiness limitations that include repetitive inspections for cracks in the lower main spar connection of the horizontal stabilizer. The FAA issued AD 2023–12–17 to address cracks in the lower main spar connection of the horizontal stabilizer and failure of certain parts, which could result in loss of airplane control.

Actions Since AD 2023–12–17 Was Issued

Since the FAA issued AD 2023–12–17, EASA superseded EASA AD 2022–0103 and issued EASA AD 2023–0184, dated October 19, 2023 (EASA AD 2023–0184) (also referred to as the MCAI) for all Pilatus Model PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes. The MCAI states that new or more restrictive tasks and limitations have been developed. These new or more restrictive airworthiness limitations include repetitive eddy current inspections for cracks in the main landing gear yoke fitting. The FAA is issuing this AD to address failure of certain parts, which could result in asymmetric main landing gear failure that could lead to loss of airplane control during take-off, landing, and taxiing operations Additionally, the actions required to address the unsafe condition in AD 2023–12–17 are included in ''the applicable ALS,'' as defined in EASA AD 2023–0184.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0045.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0184 requires certain actions and associated thresholds and intervals, including life limits and maintenance tasks. EASA AD 2023–0184 also requires doing corrective actions if any discrepancy (as defined in ''the applicable ALS'' as defined in EASA AD 2023–0184) is found during accomplishment of any task required by paragraph (1) of EASA AD 2023–0184 and revising the aircraft maintenance program (AMP) by incorporating the limitations, tasks, and associated thresholds and intervals described in ''the applicable ALS'' as defined in EASA AD 2023–0184. 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 **ADDRESSES**.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would retain none of the requirements of AD 2023–12–17. This proposed AD would require revising the ALS of the existing AMM or ICA for your airplane as specified in EASA AD 2023–0184, described previously, except as discussed under ''Differences Between this Proposed AD and EASA AD 2023–0184.''

Differences Between This Proposed AD and EASA AD 2023–0184

Paragraph (1) of EASA AD 2023–0184 requires replacing each component before exceeding the applicable life limit and within the identified thresholds and intervals accomplishing all applicable maintenance tasks as specified in the applicable ALS for that airplane. Paragraph (2) of EASA AD 2023–0184 requires corrective actions in accordance with the applicable Pilatus maintenance documentation or contacting Pilatus for approved instructions and accomplishing those instructions accordingly. Paragraph (4) of EASA AD 2023–0184 provides credit for performing actions in accordance with previous revisions of the Pilatus AMM. Paragraph (5) of EASA AD 2023–0184 explains that after revision of the AMP, it is not necessary to record accomplishment of individual actions for demonstration of AD compliance. This proposed AD would not require compliance with paragraphs (1), (2), (4), and (5) of EASA AD 2023–0184.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2023–0184 by reference in the FAA final rule. Service information required by the EASA AD for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2024–0045 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 1,030 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise the ALS	1 work-hour × $85 per hour = $85	$0	$85	$87,550

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 2023–12–17, Amendment 39–22475 (88 FR 42604, July 3, 2023); and

■ b. Adding the following new AD:

Pilatus Aircraft Ltd.: Docket No. FAA–2024–0045; Project Identifier MCAI–2023–01088–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 18, 2024.

(b) Affected ADs

This AD replaces AD 2023–12–17, Amendment 39–22475 (AD 2023–12–17).

(c) Applicability

This AD applies to Pilatus Aircraft Ltd. Model PC–12, PC–12/45, PC–12/47, and PC–12/47E airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 3211, Main Landing Gear Attach Section.

(e) Unsafe Condition

This AD was prompted by a revision to the airworthiness limitations section (ALS) of the existing aircraft maintenance manual (AMM) introducing new and more restrictive instructions and maintenance tasks as specified in the component limitations section, which include repetitive eddy current inspections for cracks in the main landing gear yoke fitting, could result in an unsafe condition. The FAA is issuing this AD to address failure of certain parts, which could result in asymmetric main landing gear failure that could lead to loss of airplane control during take-off, landing, and taxiing operations.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0184, dated October 19, 2023 (EASA AD 2023–0184).

(h) Exceptions to EASA AD 2023–0184

(1) Where EASA AD 2023–0184 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the requirements specified in paragraphs (1), (2), (4), and (5) of EASA AD 2023–0184.

(3) Where paragraph (3) of EASA AD 2023–0184 specifies ''Within 12 months after the effective date of this AD, revise the AMP,'' this AD requires replacing those words with ''Within 30 days after the effective date of this AD, revise the airworthiness limitations section of your existing airplane maintenance manual or instructions for continued airworthiness and your existing approved maintenance or inspection program, as applicable.''

(4) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2023–0184 is on or before the applicable ''limitations'' and ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2023–0184 or within 30 days after the effective date of this AD, whichever occurs later.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0184.

(i) Provisions for Alternative Actions and Intervals

No alternative actions and associated thresholds and intervals, including life limits, are allowed for compliance with paragraph (g) of this AD unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2023–0184.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Doug Rudolph, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (816) 329–4059; email: *doug.rudolph@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0184, dated October 19, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0184, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(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 January 29, 2024.

Victor Wicklund,

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

[FR Doc. 2024–02055 Filed 2–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0219; Project Identifier MCAI–2023–00764–T]

RIN 2120–AA64

Airworthiness Directives; MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. This proposed AD was prompted by a determination that a more restrictive airworthiness limitation is necessary. This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate a more restrictive airworthiness limitation, as specified in a Transport Canada AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 18, 2024.

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

- *Federal eRulemaking Portal:* Go to *regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0219; 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 Transport Canada material that is identified in this NPRM, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this material on the Transport Canada website *tc.canada.ca/en/aviation.* It is also available at *regulations.gov* under Docket No. FAA–2024–0219.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Mark Taylor, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–0219; Project Identifier MCAI–2023–00764–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, 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 Mark Taylor, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2023–41, dated June 15, 2023 (Transport Canada AD CF–2023–41) (also referred to as the MCAI), to correct an unsafe condition on certain MHI RJ Aviation ULC Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes. The MCAI states that a more restrictive airworthiness limitation has been developed due to reports of an unclear effectivity for airworthiness limitation (AWL) task number 53–41–180 in the Maintenance Requirements Manual (MRM), Part 2. If the revised task, AWL number 53–41–180, is not performed at the required intervals, failures of the strap modification to the fuselage station (FS) 409 and 128 bulkhead could remain undetected and could result in the loss of the structural integrity of the airplane.

The FAA is proposing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0219.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Transport Canada AD CF–2023–41, which specifies a more restrictive airworthiness limitation for AWL task number 53–41–180.

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 **ADDRESSES**.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the existing maintenance or inspection program, as applicable, to incorporate or a more restrictive airworthiness limitation, which is specified in Transport Canada AD CF–2023–41 described previously, as incorporated by reference. Any difference with Transport Canada AD CF–2023–41 are identified as exceptions in the regulatory text of this proposed AD.

This proposed AD would require revisions to certain operator maintenance documents to include new

actions (*e.g.,* inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this proposed AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (j)(1) of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate Transport Canada AD CF–2023–41 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2023–41 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Service information required by Transport Canada AD CF–2023–41 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–0219 after the FAA final rule is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOC paragraph under ''Additional AD Provisions.'' This new format includes a ''Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 78 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

MHI RJ Aviation ULC (Type Certificate Previously Held by Bombardier, Inc.): Docket No. FAA–2024–0219; Project Identifier MCAI–2023–00764–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 18, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to MHI RJ Aviation ULC (Type Certificate previously held by Bombardier, Inc.) Model CL–600–2B19 (Regional Jet Series 100 & 440) airplanes, certificated in any category, as identified in Transport Canada AD CF–2023–41, dated June 15, 2023 (Transport Canada AD CF–2023–41).

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that a more restrictive airworthiness limitation is necessary. The FAA is issuing this AD to address failure of the strap modification to the fuselage station (FS) 409

and 128 bulkhead. The unsafe condition, if not addressed, could result in the loss of the structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–41.

(h) Exception to Transport Canada AD CF–2023–41

(1) Where Transport Canada AD CF–2023–41 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph A. of Transport Canada AD CF–2023–41 specifies to ''incorporate the revised task AWL number 53–41–180 in Appendix B of the MRM CSP A–053 Part 2,'' this AD requires replacing those words with ''revise the existing maintenance or inspection program, as applicable, by incorporating the revised task AWL number 53–41–180 specified in MHI RJ Temporary Revision 2B–2283, dated March 16, 2023.''

(3) The initial compliance time for doing the task specified in paragraph A. of Transport Canada AD CF–2023–41 is at the applicable ''threshold'' as specified in the service information referenced in paragraph B. of Transport Canada AD CF–2023–41, or within 60 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt paragraph B. of Transport Canada AD CF–2023–41.

(i) Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Corrective Actions'' section of Transport Canada AD CF–2023–41.

(j) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (k) of this AD or email to: *9-AVS-NYACO-COS@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or MHI RJ Aviation ULC's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Additional Information

For more information about this AD, contact Mark Taylor, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2023–41, dated June 15, 2023.

(ii) [Reserved]

(3) For Transport Canada AD CF–2023–41, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this Transport Canada AD on the Transport Canada website *tc.canada.ca/en/aviation.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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

Issued on January 29, 2024.

Victor Wicklund,

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

[FR Doc. 2024–02058 Filed 2–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0042; Project Identifier MCAI–2023–00659–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Helicopters Model AS332C, AS332C1, AS3322L, AS332L1, AS332L2, and EC225LP helicopters. This proposed AD was prompted by a report of cracks on the fuel filter bowl (bowl) due to over-torquing. This proposed AD would require visually inspecting the bowls of the right hand (RH) and left hand (LH) fuel filters for any cracks and seepage. Depending on the inspection results, this proposed AD would require removing an affected fuel filter from service and replacing that part. This proposed AD would also allow a certain fuel filter to be installed on a helicopter if certain actions are accomplished, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by March 18, 2024.

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

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0042; 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 EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material identified in this NPRM, contact EASA, Konrad-Adenauer Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N 321, Fort Worth, TX

76177. For information on the availability of this material at the FAA, call (817) 222–5110. The EASA material is also available at *regulations.gov* under Docket No. FAA–2024–0042.

Other Related Service Information: For Airbus Helicopters service information identified in this NPRM, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *airbus.com/en/products-services/helicopters/hcare-services/airbusworld.* You may also view this service information at the FAA contact information under *Material Incorporated by Reference* above.

FOR FURTHER INFORMATION CONTACT: Dan McCully, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7244; email *william.mccully@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–0042; Project Identifier MCAI–2023–00659–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov,* 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 Dan McCully, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7244; email *william.mccully@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2023–0095, dated May 8, 2023 (EASA AD 2023–0095), to correct an unsafe condition on Airbus Helicopters AS 332 C, AS 332 C1, AS 332 L, AS 332 L1, AS 332 L2, and EC 225 LP helicopters, all serial numbers.

This proposed AD was prompted by a report of cracks on the bowl due to over-torquing. The FAA is proposing this AD to inspect for cracks and seepage on the bowl of the LH and RH fuel filter. The unsafe condition, if not addressed, could result in failure of the bowl, in-flight shutdown, and subsequent reduced control of the helicopter.

You may examine EASA AD 2023–0095 in the AD docket at *regulations.gov* under Docket No. FAA–2024–0042.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0095 requires a one-time inspection of the bowls of the LH and RH fuel filters for cracks and seepage. Depending on the inspection results, EASA AD 2023–0095 requires replacement of an affected part with a serviceable part, as defined in EASA AD 2023–0095. EASA AD 2023–0095 also allows certain fuel filters to be installed on a helicopter if certain actions are accomplished.

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.

Other Related Service Information

The FAA also reviewed Airbus Helicopters Alert Service Bulletin (ASB) No. AS332–28.00.88, and Airbus Helicopters ASB No. EC225–28A030, both Revision 0, and both dated April 25, 2023. This service information specifies procedures for a visual inspection the bowls on the RH and LH fuel filters for any cracks and seepage. Depending on the inspection results, this service information specifies procedures to remove and replace an affected fuel filter. This service information also specifies sending an affected fuel filter along with certain information to Airbus Helicopters, and performing an aspect check after replacement of the affected parts.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA, has notified the FAA of the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2023–0095, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and the EASA AD.''

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2023–0095 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0095 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2023–0095 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2023–0095. Service information referenced in EASA

AD 2023–0095 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–0042 after the FAA final rule is published.

Differences Between This Proposed AD and the EASA AD

EASA AD 2023–0095 requires replacing each affected fuel filter with a serviceable fuel filter if any discrepancy is detected, whereas this proposed AD would require removing each affected fuel filter from service and replacing it with a serviceable fuel filter, as described in EASA AD 2023–0095, if any crack or seepage is detected.

Service information referenced in EASA AD 2023–0095 specifies reporting certain information and sending affected parts to Airbus Helicopters, whereas this proposed AD would not require sending information or parts to Airbus Helicopters.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 40 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Inspecting each bowl for cracks (with 2 bowls per helicopter) and seepage would take approximately 1 work-hour for an estimated cost of $170 per helicopter and $6,800 for the U.S. fleet.

Replacing an affected fuel filter with a serviceable fuel filter would take approximately 1 work-hour and parts would cost approximately $6,290 for an estimated cost of $6,375 per fuel filter replacement.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2024–0042; Project Identifier MCAI–2023–00659–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 18, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Model AS332C, AS332C1, AS332L, AS332L1, AS332L2, and EC225LP helicopters, certificated in any category,

(d) Subject

Joint Aircraft Service Component (JASC) Code: 2821, Aircraft fuel filter/strainer.

(e) Unsafe Condition

This AD was prompted by a report of cracks on the fuel filter bowl (bowl) due to over-torquing. The FAA is proposing this AD to inspect for cracks and seepage on the bowl of the left-hand (LH) and right-hand (RH) fuel filter. The unsafe condition, if not addressed, could result in failure of the bowl, in-flight shutdown, and subsequent reduced control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0095, dated May 8, 2023 (EASA AD 2023–0095).

(h) Exceptions to EASA AD 2023–0095

(1) Where EASA AD 2023–0095 requires compliance in terms of flight hours, this AD requires using hours time-in-service.

(2) Where EASA AD 2023–0095 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraph (1) of EASA AD 2023–0095 requires an inspection ''in accordance with the instructions of the applicable ASB,'' for this AD, replace that text with, ''in accordance with paragraph 3.B.2.a. of the applicable ASB, except you are not required to comply with paragraph 3.B.2.b or 3.B.3.''

(4) Where paragraph (2) of EASA AD 2023–0095 states ''replace the affected part with a serviceable part in accordance with the instructions of the applicable ASB,'' this AD requires replacing those words with ''remove the affected part from service and replace it with a serviceable part.''

(5) Where the service information referenced in EASA AD 2023–0095 specifies to ''make sure that there is no crack and no seepage on the bowls (a) of the RH and LH fuel filters (b),'' this AD requires replacing those words with ''Inspect for any crack and seepage on the bowls (a) of the RH and LH fuel filters (b).''

(6) Where the service information referenced in EASA AD 2023–0095 specifies ''If there is a crack and/or a seepage on the bowls (a) of the RH and LH fuel filters (b), comply with paragraph 3.B.2.b.,'' this AD requires replacing that text with ''If there is a crack or seepage on the bowls (a) of the RH or LH fuel filter (b), before further flight, remove the affected part from service and replace with a serviceable part, as defined in EASA AD 2023–0095.''

(7) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0095.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2023–0095 specifies to submit certain information and return parts to the manufacturer, this AD does not include those requirements.

(j) Special Flight Permit

Special flight permits are prohibited.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve

AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(l) Related Information

For more information about this AD, contact Dan McCully, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone (781) 238–7244; email *william.mccully@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0095, dated May 8, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0095, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on January 26, 2024.

Michael Linegang,

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

[FR Doc. 2024–01989 Filed 2–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0038; Project Identifier MCAI–2023–00645–R]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters. This proposed AD was prompted by a report of an obstructed tail rotor (TR) pedal control that was blocked during flight. This proposed AD would require a one-time inspection for proper positioning of the TR actuator harness and cable ties installation and, depending on the results, accomplishing corrective action, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by March 18, 2024.

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

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0038; 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 EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference

- For EASA material identified in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*
- You may view this service information at the FAA Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. The EASA material is also available at *regulations.gov* under Docket No. FAA–2024–0038.

Other Related Service Information: For Airbus Helicopters service information identified in this NPRM, contact Airbus Helicopters, 2701 North Forum Drive, Grand Prairie, TX 75052; phone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *airbus.com/en/products-services/helicopters/hcare-services/airbusworld.* You may also view this service information at the FAA contact information under *Material Incorporated by Reference* above.

FOR FURTHER INFORMATION CONTACT: Dan McCully, Program Manager, International Validation Branch, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (404) 474–5548; email: *william.mccully@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–0038; Project Identifier MCAI–2023–00645–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov,* 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 Dan McCully, Program Manager, International Validation Branch, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (404) 474–5548; email: *william.mccully@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2023–0090, dated May 4, 2023 (EASA AD 2023–0090), to correct an unsafe condition on Airbus Helicopters Model SA 365 N, SA 365 N1, AS 365 N2, and AS 365 N3 helicopters. EASA advises of a report where a TR pedal control was blocked during flight. Subsequent investigation found interference between the cable tie head of the TR actuator harness and the pin fastener of the tail gearbox cowling. To address this unsafe condition, the manufacturer issued service information to provide instructions for inspecting the positioning of the cable ties on the yaw harness.

The FAA is proposing this AD to detect and address interference of the TR pedal control. This unsafe condition, if not addressed could result in loss of yaw control of the helicopter. See EASA AD 2023–0090 for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2023–0090 requires visually inspecting the position of the cable tie heads of the harness and corrective actions (replacing the cable ties) if necessary.

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.

Other Related Service Information

The FAA also reviewed Airbus Helicopters Alert Service Bulletin No. AS365–22.00.17, Revision 1, dated June 27, 2023. This service information specifies procedures for accomplishing a one-time check of the position of the two cable tie heads in relation to the dzus prisoner of the right fairing of the tail gearbox, and replacing the cable ties if necessary.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of these same type designs.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2023–0090 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0090 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2023–0090 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2023–0090. Service information referenced in EASA AD 2023–0090 for compliance will be available at *www.regulations.gov* by searching for and locating Docket No. FAA–2024–0038 after the FAA final rule is published.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2023–0090, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD and except as discussed under ''Differences Between this Proposed AD and EASA AD 2023–0090.''

Differences Between This Proposed AD and EASA AD 2023–0090

EASA AD 2023–0090 requires accomplishing the inspection within 165 flight hours, whereas this proposed AD would require accomplishing the inspection within 100 hours time-in-service.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 29 helicopters of U.S. registry. Labor costs are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this proposed AD.

Visually inspecting the position of the cable ties on the yaw harness and interpreting the results would take about 1 work-hour for an estimated cost of $85 per helicopter and $2,465 for the U.S. fleet.

The FAA estimates the following costs to do any necessary repairs that would be required based on the results of the proposed inspection. The agency has no way of determining the number of helicopters that might need this repair.

If required, removing and replacing a cable tie would take about 0.5 work-hour and parts would cost up to about $10 for an estimated cost of $53 per cable tie replacement.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2024–0038; Project Identifier MCAI–2023–00645–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by March 18, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report of an obstructed tail rotor (TR) pedal control that was blocked during flight. The FAA is issuing this AD to detect and address interference of the tail rotor pedal control. The unsafe condition, if not addressed, could result in loss of yaw control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2023–0090, dated May 4, 2023 (EASA AD 2023–0090).

(h) Exceptions to EASA AD 2023–0090

(1) Where paragraph (1) of EASA AD 2023–0090 requires compliance within 165 flight hours, this AD requires accomplishing paragraph (1) of EASA AD 2023–0090 within 100 hours time-in-service.

(2) Where EASA AD 2023–0090 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where the service information referenced in EASA AD 2023–0090 specifies discarding parts, this AD requires removing those parts from service.

(4) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0090.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2023–0090 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: *9-AVS-AIR-730-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) Related Information

For more information about this AD, contact Dan McCully, Program Manager, International Validation Branch, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; phone: (404) 474–5548; email: *william.mccully@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2023–0090, dated May 4, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0090 identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *easa.europa.eu.* You may find the EASA material on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on January 24, 2024.

Victor Wicklund,

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

[FR Doc. 2024–01754 Filed 2–1–24; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 146

RIN 3038–AF22

Privacy Act Regulations

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commodity Futures Trading Commission (CFTC or Commission) proposes to update its regulations regarding exemptions for certain systems of records from one or more provisions of the Privacy Act of 1974 (Privacy Act). The Commission proposes to revise these regulations to specifically identify the systems of records currently included in the regulation that the Commission is exempting, additional systems of records that the Commission intends to exempt, and the sections of the Privacy Act from which the Commission is exempting each system of records, and the reasons therefor, in order to better conform to the requirements of the Privacy Act and the guidance contained in Office of Management and Budget (OMB) Circular A–108, *Federal Agency Responsibilities for Review, Reporting, and Publication Under the Privacy Act* (OMB A–108). The Commission also proposes to reorganize the regulations for ease of reference.

DATES: Please submit comments on or before March 4, 2024.

ADDRESSES: You may submit comments identified as pertaining to ''Privacy Act Regulations'' by any of the following methods:

- *CFTC Comments Portal: https://comments.cftc.gov.* Select the ''Submit Comments'' link for this rulemaking and follow the instructions on the Public Comment Form.
- *Mail:* Send to Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Follow the same instructions as for Mail, above.

Please submit your comments using only one of these methods. To avoid possible delays with mail or in-person deliveries, submissions through the CFTC Comments Portal are encouraged.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. 552, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in the Commission's regulations at 17 CFR 145.9.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse, or remove any or all of a submission from *www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the notice will be retained in the comment file and will be considered as required under the Administrative Procedure Act (APA), and may be accessible under FOIA.

FOR FURTHER INFORMATION CONTACT: Kellie Cosgrove Riley, Chief Privacy Officer, *privacy@cftc.gov,* 202–418–5610, Office of the General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Privacy Act

The Privacy Act of 1974 [1] establishes a code of fair information practice principles that govern Federal agencies' collection, maintenance, use, and dissemination of an individual's personal information. The Privacy Act applies to information that is maintained in a ''system of records,'' defined as a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.[2]

In addition to establishing a code of fair information practice principles, the Privacy Act restricts disclosure of records containing personal information that an agency maintains.[3] The Privacy Act also grants individuals an increased right of access to records maintained about themselves as well as the right to request amendment of those records upon a showing that they are not accurate, relevant, timely, or complete.[4]

B. Privacy Act Exemptions

The Privacy Act permits agencies, where certain requirements are met and subject to limitations set forth in the Privacy Act, to specifically exempt systems of records from certain provisions of the Privacy Act, mainly pertaining to the Privacy Act's provisions permitting individuals to access and request amendment of their records.[5] In order to claim an exemption, however, the agency must engage in a rulemaking process pursuant to the APA [6] and make clear to the public why particular exemptions are being invoked.[7]

Part 146 of the Commission's regulations,[8] entitled ''Records Maintained on Individuals,'' contains the rules of the Commission implementing the Privacy Act. Commission regulations §§ 146.12 and 146.13 (together, Privacy Act regulations) currently assert exemptions for certain of the Commission's systems of records that contain records related to the Commission's investigatory mission and personnel security obligations. After reviewing those regulations, the Commission has preliminarily determined that the current Privacy Act regulations do not include all of the systems of records for which the Commission would, in fact, assert exemptions, and those systems of records that are currently referenced are not clearly identified with each system of records' number and accurate title. The Commission has also preliminarily determined to add more specificity regarding the rationale for exempting each of the systems of records in order to better demonstrate the Commission's compliance with subsections (j) and (k) of the Privacy Act [9] and the corresponding guidance in OMB Circular A–108.[10] OMB A–108, issued in 2016, provides that, at minimum, an agency's Privacy Act exemption regulations shall include the specific name of any systems of records that will be exempt pursuant to the regulations, the specific provisions of the Privacy Act from which the systems of records will be exempt and the reasons therefor, and an explanation of why the exemption is necessary and appropriate.[11] Accordingly, the Commission proposes to replace current § 146.12 of the Commission's regulations with a more detailed provision that would more specifically identify all of the systems of records it proposes to exempt, the specific provisions of the Privacy Act from which each system of records is being exempted, and the reasons why the Commission is adopting those exemptions. Moreover, the Commission has preliminarily concluded that a separate Privacy Act regulation § 146.13 for exemptions taken for an Office of the Inspector General (OIG) system of records is not required by the Privacy Act or OMB guidance. Accordingly, the Commission proposes to remove current Commission regulation § 146.13 and add the OIG exemptions to proposed Commission regulation § 146.12, with revisions to the content as explained below.

C. Specific Exempted Systems of Records

1. CFTC–1 Enforcement Matter Register and Matter Indices (CFTC–1)

CFTC–1 contains an index and registry of enforcement investigations. This system of records is not currently identified in Commission regulation § 146.12 as a system of records that the Commission has exempted. The Commission is proposing to exempt this system of records because the records

[1] 5 U.S.C. 552a.
[2] 5 U.S.C. 552a(a)(5).
[3] 5 U.S.C. 552a(b).
[4] 5 U.S.C. 552a(d).
[5] 5 U.S.C. 552a(j) and (k).
[6] 5 U.S.C. 553.
[7] 5 U.S.C. 552a(j) and (k).
[8] 17 CFR 146.
[9] 5 U.S.C. 552a(j) and (k).
[10] OMB A–108, available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A108/omb_circular_a-108.pdf,* at page 25.
[11] OMB A–108 at page 25.

are compiled for law enforcement purposes and must be protected from disclosure in order to maintain the integrity of the investigative process and not provide to any individual an opportunity to access records and compromise that process, such as through the destruction of evidence, interference with witnesses, or otherwise. In addition, the Commission is proposing to exempt this system of records in order to keep confidential the identity of sources who provided information to the Commission during the course of the investigation under an express promise that their identities would remain confidential. If an individual can access the identities of confidential sources, those sources may be unwilling to provide information that the Commission needs for its law enforcement activities. Specifically, the Commission is proposing to exempt CFTC–1, pursuant to subsection (k)(2) of the Privacy Act [12] and subject to the requirements and limitations set forth therein, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

Request for Comment

The Commission requests comment on the justification for and scope of the proposed CFTC–1 exemptions.

2. CFTC–10 Investigatory Records (CFTC–10)

CFTC–10 contains records compiled for law enforcement purposes, including records developed during an investigation of violations or potential violations of the Commodity Exchange Act.[13] This system of records is included in the current Commission regulation § 146.12 but is identified as ''Exempted Investigatory Records'' and the exemptions identified in the current regulation lack the specificity that the Commission is proposing to include in new regulation § 146.12. The Commission is proposing to identify this system of records by its proper title and number and set forth the specific reasons for which it is being exempted from particular provisions of the Privacy Act. To that end, the Commission is proposing to explain in revised Commission regulation § 146.12 that this system of records is being exempted because the records must be protected from disclosure in order to maintain the integrity of the investigative process and not provide an individual an opportunity to access records and compromise that process, such as through the destruction of evidence, interference with witnesses, or otherwise. In addition, the Commission is proposing to exempt this system of records in order to keep confidential the identity of sources who provided information to the Commission during the course of the investigation under an express promise that their identities would remain confidential. If an individual can access the identities of confidential sources, those sources may be unwilling to provide information that the Commission needs for its law enforcement activities. Specifically, the Commission is proposing to exempt CFTC–10, pursuant to subsection (k)(2) of the Privacy Act [14] and subject to the requirements and limitations set forth therein, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

Request for Comment

The Commission requests comment on the justification for and scope of the CFTC–10 exemptions.

3. CFTC–12 National Futures Association (NFA) Applications Suite System (CFTC–12)

CFTC–12 contains records held by NFA on behalf of the Commission by delegated authority to support the Commission's registration and other regulatory authority. These records include records pertaining to the fitness of individuals to be registered with the Commission and engage in business activities that are subject to the Commission's jurisdiction and records pertaining to disciplinary or other adverse action investigated or taken with respect to individual registrants. This system of records is not currently identified in Commission regulation § 146.12 as a system of records that the Commission has exempted. The Commission is proposing to exempt this system of records because to the extent the records pertaining to individuals that NFA holds on behalf of the Commission are investigatory records compiled for law enforcement purposes, they must be protected from disclosure in order to maintain the integrity of the investigative process and not provide to any individual an opportunity to access records and compromise that process, such as through the destruction of evidence, interference with witnesses, or otherwise. In addition, the Commission is proposing to exempt this system of records in order to keep confidential the identity of sources who provided information to NFA acting on behalf of the Commission during the course of the investigation under an express promise that their identities would remain confidential. If an individual can access the identities of confidential sources, those sources may be unwilling to provide information that the Commission needs for its law enforcement activities. Specifically, the Commission is proposing to exempt CFTC–12, pursuant to subsection (k)(2) of the Privacy Act [15] and subject to the requirements and limitations set forth therein, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

Request for Comment

The Commission requests comment on the justification for and scope of the CFTC–12 exemptions.

4. CFTC–31 Closed Commission Meetings (CFTC–31)

CFTC–31 contains records about individuals who are the subject of discussion at closed Commission meetings, including those who are the subject of investigations or who are being considered for employment. This system of records is included in the current Commission regulation § 146.12 but identified as ''Exempted Closed Commission Meetings'' and the exemptions identified in the current regulation lack the specificity that the Commission is proposing to include in new regulation § 146.12. The Commission is proposing to identify this system of records by its proper title and number and to set forth the specific reasons for which it is being exempted from particular provisions of the Privacy Act. To that end, to the extent the records in this system of records pertain to law enforcement investigations, the Commission is proposing to exempt this system of records because the records must be protected from disclosure in order to maintain the integrity of the investigative process and not to provide to any individual an opportunity to compromise that process, such as through the destruction of evidence, interference with witnesses, or otherwise. In addition, the Commission is proposing to exempt this system of records in order to keep confidential the identity of sources who provided information to the Commission during the course of the investigation under an express promise that their identities would remain confidential. If an individual can access the identities of confidential sources, those sources may be unwilling to provide information that

[12] 5 U.S.C. 552a(k)(2).

[13] 7 U.S.C. 1 *et seq.*

[14] 5 U.S.C. 552a(k)(2).

[15] 5 U.S.C. 552a(k)(2).

the Commission needs for its law enforcement activities. Finally, to the extent records in this system of records are compiled solely for the purpose of determining the suitability, eligibility, or qualifications of an individual who is being considered for employment with the Commission, the Commission is proposing to exempt this system of records where the disclosure of records would reveal the identity of somebody who provided information in the context of the Commission's determination and who had expressly requested that their identity remain confidential. The Commission has preliminarily determined that such an exemption is necessary in order to obtain information relevant to its eligibility determinations. Accordingly, the Commission is proposing to exempt CFTC–31, pursuant to subsections (k)(2) and (k)(5) of the Privacy Act [16] and subject to the requirements and limitations set forth therein, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

Request for Comment

The Commission requests comment on the justification for and scope of the CFTC–31 exemptions.

5. CFTC–32 Office of the Inspector General Investigative Files (CFTC–32)

CFTC–32 contains records relevant to criminal and civil investigations conducted by the Office of the Inspector General (OIG). This system of records is included in the current Commission regulation § 146.13 with exemptions promulgated pursuant to subsections (j)(2) and (k)(2) of the Privacy Act, the former for records related to the OIG's criminal law enforcement activities and the latter for investigatory records compiled for law enforcement purposes not within the scope of subsection (j)(2). The Commission has preliminarily concluded that a separate Privacy Act regulation § 146.13 for exemptions taken for this OIG system of records is not required by the Privacy Act or OMB guidance. Accordingly, the Commission, after consultation with the OIG, proposes to remove current Commission regulation § 146.13 and incorporate the exemptions for CFTC–32 into proposed Commission regulation § 146.12. Moreover, the Commission is proposing to set forth the specific reasons for which this system of records is being exempted from particular provisions of the Privacy Act. To that end, the Commission is proposing to explain in revised Commission regulation § 146.12 that this system of records is being exempted because the records must be protected from disclosure in order to maintain the integrity of the investigative process and not provide to any individual an opportunity to access records and compromise that process, such as through the destruction of evidence, interference with witnesses, or otherwise. In addition, the Commission is proposing to exempt this system of records in order to keep confidential the identity of sources who provided information to the Commission during the course of the investigation under an express promise that their identities would remain confidential. If an individual can access the identities of confidential sources, those sources may be unwilling to provide information that the Commission needs for its law enforcement activities, federal employee and contractor witnesses may risk retaliation in the federal workplace, and any witness may risk witness interference tactics including threats, harassment, and physical and emotional harm. Specifically, the Commission is proposing to exempt this system of records, pursuant to subsection (j)(2) of the Privacy Act [17] and subject to the requirements and limitations set forth therein, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3) and (4); (d)(1), (2), (3), and (4); (e)(1), (2), (3), (4)(G)–(I), (5), and (8); (f); and (g). In addition, the Commission is proposing to exempt this system of records, pursuant to subsection (k)(2) of the Privacy Act [18] and subject to the requirements and limitations set forth therein, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

Request for Comment

The Commission requests comment on the justification for and scope of the CFTC–32 exemptions. The Commission also requests comment on whether the CFTC–32 exemptions should be included in proposed Commission regulation § 146.12 or remain in separate Commission regulation § 146.13.

6. CFTC–44 Personnel Clearance System (CFTC–44)

CFTC–44 contains records related to the background investigations and security clearances of individuals who have been or are being considered for access to Commission facilities, information technology systems, and classified or confidential information. These records may include statements from individuals who have provided information in the course of a background investigation and have requested that their identity remain confidential, and records that constitute investigatory materials compiled for law enforcement purposes. This system of records is identified in current regulation § 146.12 by its predecessor name, ''Exempted Employee Background Investigation Material,'' and the current regulation exempts the system of records only pursuant to subsection (k)(5) of the Privacy Act. The Commission is proposing to identify this system of records by its proper title and number and to set forth the specific reasons for which it is being exempted from particular provisions of the Privacy Act pursuant to both subsection (k)(2) and (k)(5) of the Privacy Act.[19] To that end, to the extent records in this system of records are compiled solely for the purpose of determining an individual's suitability, eligibility, or qualifications for employment with the Commission, the Commission is proposing to explain in the revised Commission regulation § 146.12 that this system of records is exempt where the disclosure of records would reveal the identity of somebody who provided information in the context of the Commission's determination and who had expressly requested that their identity remain confidential in order to maintain the promised confidentiality and enable the Commission to obtain information relevant to its eligibility determinations. In addition, to the extent records in this system of records pertain to law enforcement investigations, the Commission is proposing to exempt this system of records because the records must be protected from disclosure in order to maintain the integrity of the investigative process and not provide to any individual the opportunity to compromise that process, such as through the destruction of evidence, interference with witnesses, or otherwise. The Commission is also proposing to exempt this system of records in order to keep confidential the identity of sources who provided information to the Commission during the course of the investigation under an express promise that their identities would remain confidential. If an individual can access the identities of confidential sources, those sources may be unwilling to provide information that the Commission needs for its law enforcement activities. Specifically, the Commission is proposing to exempt this

[16] 5 U.S.C. 552a(k)(2) and (k)(5), respectively.

[17] 5 U.S.C. 552a(j)(2).

[18] 5 U.S.C. 552a(k)(2).

[19] 5 U.S.C. 552a(k)(2) and (k)(5).

system of records, pursuant to subsections (k)(2) and (k)(5) of the Privacy Act [20] and subject to the requirements and limitations set forth therein, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

Request for Comment

The Commission requests comment on the justification for and scope of the CFTC–44 exemptions.

7. CFTC–49 Whistleblower Records (CFTC–49)

CFTC–49 contains records related to whistleblower tips, complaints and referrals, records related to investigations and inquiries into whistleblower complaints, and records related to the whistleblower award claim and determination process. This system of records is not currently identified in Commission regulation § 146.12 as a system of records that the Commission has exempted. The Commission is proposing to exempt this system of records because the records are compiled for law enforcement purposes and must be protected from disclosure in order to maintain the integrity of the whistleblower process and not provide to any individual an opportunity to access records and compromise an investigation, such as through the destruction of evidence, interference with witnesses, or otherwise. In addition, the Commission is proposing to exempt this system of records in order to keep confidential the identity of sources who provided information during the course of the investigation under an express promise that their identities would remain confidential. If an individual can access the identities of confidential sources, those sources may be unwilling to provide information that the Commission needs to investigate whistleblower tips, complaints, and referrals. Specifically, the Commission proposes to exempt this system of records, pursuant to subsection (k)(2) of the Privacy Act [21] and subject to the requirements and limitations set forth therein, from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

Request for Comment

The Commission requests comment on the justification for and scope of the CFTC–49 exemptions.

[20] 5 U.S.C. 552a(k)(2) and (k)(5).

[21] 5 U.S.C. 552a(k)(2).

II. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires federal agencies to consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, to provide a regulatory flexibility analysis regarding the economic impact on those entities.[22]

The proposed regulations, issued under the Privacy Act, exempt certain systems of records maintained by the Commission from certain provisions of the Privacy Act, primarily those provisions related to an individual's right to access and seek amendment of those records. Individuals are defined in the Privacy Act as United States citizens or aliens lawfully admitted to the United States for permanent residence.[23] Small entities, as defined in the RFA, are not individuals under the Privacy Act and are not provided rights thereunder; therefore, small entities are outside the scope of the proposed regulations. Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b), that this proposed rule will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) imposes certain requirements on federal agencies in connection with their conducting or sponsoring any collection of information.[24] The Commission may not conduct or sponsor, and a respondent is not required to respond to, a request for collection of information unless the information collection request displays a currently valid control number issued by OMB. This proposed rule does not contain a ''collection of information,'' as defined in the PRA. Accordingly, the requirements imposed by the PRA are not applicable to this proposed rule.

C. Cost-Benefit Considerations

Section 15(a) of the Commodity Exchange Act (CEA) provides that, before promulgating a regulation under the CEA or issuing an order, the Commission shall consider the costs and benefits of the action of the Commission.[25] Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of the futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations.[26] The proposed rules are being promulgated under the Privacy Act and pertain to the rights of individuals with respect to records the Commission maintains about them. The proposed rules are not being promulgated under the CEA. Therefore, the Commission preliminarily finds that the considerations enumerated in section 15(a)(2) of the CEA are not applicable here.

Request for Comment

The Commission requests comment on whether its preliminary finding is correct.

D. Antitrust Considerations

Section 15(b) of the CEA requires the Commission to take into consideration the public interest to be protected by the antitrust laws and endeavor to take the least anticompetitive means of achieving the purposes of the CEA, in issuing any order or adopting any Commission rule or regulation (including any exemption under section 4(c) or 4c(b)), or in requiring or approving any bylaw, rule, or regulation of a contract market or registered futures association established pursuant to section 17 of the CEA.[27] The Commission believes that the public interest to be protected by the antitrust laws is generally to protect competition. The Commission has considered the proposed rule to determine whether it is anticompetitive and has preliminarily identified no anticompetitive effects.

Because the Commission has preliminarily determined that the proposed rule is not anticompetitive and has no anticompetitive effects, the Commission has not identified any less anticompetitive means of achieving the purposes of the Act.

Request for Comment

The Commission requests comment on whether the proposed rule is anticompetitive and, if it is, what the anticompetitive effects are and whether there are less anticompetitive means of achieving the relevant purposes of the Act that would otherwise be served by adopting the proposed rule. The Commission also requests comment on whether the proposed rule implicates any other specific public interest to be protected by the antitrust laws.

[22] 5 U.S.C. 601 *et seq.*

[23] 5 U.S.C. 552a(a)(2).

[24] 5 U.S.C. 3501 *et seq.*

[25] 7 U.S.C. 19(a).

[26] 7 U.S.C. 19(a)(2).

[27] 7 U.S.C. 19(b).

List of Subjects in 17 CFR Part 146

Privacy.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR part 146 as follows:

PART 146—RECORDS MAINTAINED ON INDIVIDUALS

■ 1. The authority citation for part 146 continues to read as follows:

Authority: 88 Stat. 1896 (5 U.S.C. 552a), as amended; 88 Stat. 1389 (7 U.S.C. 4a(j)).

■ 2. Revise § 146.12 to read as follows:

§ 146.12 Exemptions.

The Commission is exempting from certain provisions of the Privacy Act the systems of records set forth in this section. In addition, when these systems of records and any other of the Commission's systems of records maintain a record received from another system of records that is exempted from one or more provisions of the Privacy Act, the Commission will claim the same exemptions for that record that are claimed for the system of records from which it originated.

(a) *CFTC–1 Enforcement Matter Register and Matter Indices.* The system of records identified as CFTC–1 Enforcement Matter Register and Matter Indices contains an index and registry of enforcement investigations. Pursuant to 5 U.S.C. 552a(k)(2) and subject to the requirements and limitations set forth therein, the Commission is exempting this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f), and from the following corresponding sections of this part: 146.3; 146.5; 146.6(d); 146.11(a)(7), (8), and (9); and 146.7(a). Exemptions from these particular subsections of the Privacy Act and sections of this part promulgated thereunder are justified for the following reasons:

(1) From subsection (c)(3) (Accounting of Certain Disclosures), because release of the accounting of certain disclosures could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and the recipient entity. Release of such information to the subject of an investigation could reasonably be anticipated to impede and interfere with the Commission's efforts to identify and investigate unlawful activities.

(2) From subsection (d)(1), (2), (3), and (4) (Access and Amendment), because individual access to these records could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and others. Providing a subject with access to these records could impair the effectiveness of the Commission's investigations and could significantly impede the investigation by providing the opportunity for the subject to destroy documentary evidence, improperly influence witnesses and confidential sources, fabricate testimony, and engage in other activities that could compromise the investigation. In addition, providing an individual with access to these records may reveal the identity of a source who furnished information under an express promise that their identity would remain confidential. Allowing the subject of the investigation to amend records in this system of records could likewise interfere with ongoing law enforcement proceedings and impose an impossible administrative burden by requiring law enforcement investigations to be continuously reinvestigated.

(3) From subsection (e)(1) (Relevancy and Necessity of Information), because in the course of investigations into potential violations of law, the significance of certain information may not be clear or the information may not be strictly relevant or necessary to a specific investigation; but, effective law enforcement requires the retention of all information that may aid in establishing patterns of unlawful activity and providing investigative leads.

(4) From subsection (e)(4)(G), (H), and(I) (Agency Requirements) and (f) (Agency Rules), because the Commission is not required to establish requirements, rules, or procedures related to access and amendment of records in a system of records that is exempt from the individual access and amendment provisions in subsection (d) of the Privacy Act.

(b) *CFTC–10 Investigatory Records.* The system of records identified as CFTC–10 Investigatory Records contains records compiled for law enforcement purposes, including records developed during an investigation of violations or potential violations of the Commodity Exchange Act. Pursuant to 5 U.S.C. 552a(k)(2) and subject to the requirements and limitations set forth therein, the Commission is exempting this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f), and from the following corresponding sections of this part: 146.3; 146.5; 146.6(d); 146.11(a)(7), (8), and (9); and 146.7(a). Exemptions from these particular subsections of the Privacy Act and sections of this part promulgated thereunder are justified for the following reasons:

(1) From subsection (c)(3) (Accounting of Certain Disclosures), because release of the accounting of certain disclosures could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and the recipient entity. Release of such information to the subject of an investigation could reasonably be anticipated to impede and interfere with the Commission's efforts to identify and investigate unlawful activities.

(2) From subsection (d)(1), (2), (3), and (4) (Access and Amendment), because individual access to these records could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and others. Providing a subject with access to these records could impair the effectiveness of the Commission's investigations and could significantly impede the investigation by providing the opportunity for the subject to destroy documentary evidence, improperly influence witnesses and confidential sources, fabricate testimony, and engage in other activities that could compromise the investigation. In addition, providing an individual with access to these records may reveal the identity of a source who furnished information under an express promise that their identity would remain confidential. Allowing the subject of the investigation to amend records in this system of records could likewise interfere with ongoing law enforcement proceedings and impose an impossible administrative burden by requiring law enforcement investigations to be continuously reinvestigated.

(3) From subsection (e)(1) (Relevancy and Necessity of Information), because in the course of investigations into potential violations of law, the significance of certain information may not be clear or the information may not be strictly relevant or necessary to a specific investigation; but, effective law enforcement requires the retention of all information that may aid in establishing patterns of unlawful activity and providing investigative leads.

(4) From subsection (e)(4)(G), (H), and(I) (Agency Requirements) and (f) (Agency Rules), because the Commission is not required to establish

requirements, rules, or procedures related to access and amendment of records in a system of records that is exempt from the individual access and amendment provisions in subsection (d) of the Privacy Act.

(c) *CFTC–12 National Futures Association (NFA) Applications Suite System.* The system of records identified as CFTC–12 National Futures Association (NFA) Applications Suite System contains records held by NFA on behalf of the Commission, by delegated authority to support the Commission's registration and other regulatory authority. These records include records pertaining to the fitness of individuals to be registered with the Commission and engage in business activities that are subject to the Commission's jurisdiction and records pertaining to disciplinary or other adverse action investigated or taken with respect to individual registrants. Pursuant to 5 U.S.C. 552a(k)(2) and subject to the requirements and limitations set forth therein, the Commission is exempting this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f), and from the following corresponding sections of this part: 146.3; 146.5; 146.6(d); 146,11(a)(7), (8), and (9); and 146.7(a). Exemptions from these particular subsections of the Privacy Act are justified for the following reasons:

(1) From subsection (c)(3) (Accounting of Certain Disclosures), because release of accountings of certain disclosures could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and the recipient entity. Release of such information to the subject of an investigation could reasonably be anticipated to impede and interfere with the Commission's efforts to identify and investigate unlawful activities.

(2) From subsection (d)(1), (2), (3), and (4) (Access and Amendment), because individual access to these records could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and others. Providing a subject with access to these records could impair the effectiveness of the Commission's investigations and could significantly impede the investigation by providing the opportunity for the subject to destroy documentary evidence, improperly influence witnesses and confidential sources, fabricate testimony, and engage in other activities that could compromise the investigation. In addition, providing an individual with access to these records may reveal the identity of a source who furnished information under an express promise that their identity would remain confidential. Allowing the subject of the investigation to amend records in this system of records could likewise interfere with ongoing law enforcement proceedings and impose an impossible administrative burden by requiring law enforcement investigations to be continuously reinvestigated.

(3) From subsection (e)(1) (Relevancy and Necessity of Information), because in the course of investigations into potential violations of law, the significance of certain information may not be clear or the information may not be strictly relevant or necessary to a specific investigation; but, effective law enforcement requires the retention of all information that may aid in establishing patterns of unlawful activity and providing investigative leads.

(4) From subsection (e)(4)(G), (H), and (I) (Agency Requirements) and (f) (Agency Rules), because the Commission is not required to establish requirements, rules, or procedures related to access and amendment of records in a system of records that is exempt from the individual access and amendment provisions in subsection (d) of the Privacy Act.

(d) *CFTC–31 Closed Commission Meetings.* The system of records identified as CFTC–31 Closed Commission Meetings contains records about individuals who are the subject of discussion at closed Commission meetings, including those who are the subject of investigations or who are being considered for employment. These records may include statements from individuals who have provided information in the course of an applicant's or employee's background investigation or other Commission investigation and who have requested that their identities remain confidential. Pursuant to 5 U.S.C. 552a(k)(2) and (k)(5) and subject to the requirements and limitations set forth therein, the Commission is exempting this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f), and from the following corresponding sections of this part: 146.3; 146.5; 146.6(d); 146.11(a)(7), (8), and (9); and § 146.7(a). Exemptions from these particular subsections of the Privacy Act are justified for the following reasons:

(1) From subsection (c)(3) (Accounting of Certain Disclosures), because release of the accounting of certain disclosures could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and the recipient entity. Release of such information to the subject of an investigation could reasonably be anticipated to impede and interfere with the Commission's efforts to identify and investigate unlawful activities.

(2) From subsection (d)(1), (2), (3), and (4) (Access and Amendment), because individual access to these records could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and others. Providing a subject with access to these records could impair the effectiveness of the Commission's investigations and could significantly impede the investigation by providing the opportunity for the subject to destroy documentary evidence, improperly influence witnesses and confidential sources, fabricate testimony, and engage in other activities that could compromise the investigation. In addition, providing an individual with access to these records may reveal the identity of a source who furnished information under an express promise that their identity would remain confidential. Allowing the subject of the investigation to amend records in this system of records could likewise interfere with ongoing law enforcement proceedings and impose an impossible administrative burden by requiring law enforcement investigations to be continuously reinvestigated.

(3) From subsection (e)(1) (Relevancy and Necessity of Information), because in the course of investigations into potential violations of law, the significance of certain information may not be clear or the information may not be strictly relevant or necessary to a specific investigation; but, effective law enforcement requires the retention of all information that may aid in establishing patterns of unlawful activity and providing investigative leads.

(4) From subsection (e)(4)(G), (H), and (I) (Agency Requirements) and (f) (Agency Rules), because the Commission is not required to establish requirements, rules, or procedures related to access and amendment of records in a system of records that is exempt from the individual access and amendment provisions in subsection (d) of the Privacy Act.

(e) *CFTC–32, Office of the Inspector General Investigative Files.* The system

of records identified as CFTC–32 Office of the Inspector General Investigative Files contains records relevant to criminal and civil investigations conducted by the Office of the Inspector General, including records about individuals being investigated for fraudulent and abusive activities. Pursuant to 5 U.S.C. 552a(j)(2) and subject to the requirements and limitations set forth therein, the Commission is exempting this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3) and (4); (d)(1), (2), (3), and (4); (e)(1), (2), (3), (4)(G)–(I), (5), and (8); (f); and (g), and from the following corresponding sections of this part: 146.3; 146.4; 146.5; 146.6(b), (d), and (e); 146.7(a), (c), and (d); 146.8; 146.9; 146.10; and 146.11(a)(7), (8), and (9). In addition, pursuant to 5 U.S.C. 552a(k)(2) and subject to the requirements and limitations set forth therein, the Commission is exempting this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f), and from the following corresponding sections of this part: 146.3; 146.5; 146.6(d); 146.11(a)(7), (8), and (9); and 146.7(a). Exemptions from these particular subsections of the Privacy Act are justified for the following reasons:

(1) From subsection (c)(3) (Accounting of Certain Disclosures), because release of the accounting of certain disclosures could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and the recipient entity. Release of such information to the subject of an investigation could reasonably be anticipated to impede and interfere with the Commission's efforts to identify and investigate unlawful activities.

(2) From subsection (c)(4) (Notice of Correction), because this system is exempt from the access and amendment provisions of subsection (d), as noted in paragraph (e)(3) of this section.

(3) From subsection (d)(1), (2), (3), and (4) (Access and Amendment), because individual access to these records could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and others. Providing a subject with access to these records could impair the effectiveness of the Commission's investigations and could significantly impede the investigation by providing the opportunity for the subject to destroy documentary evidence, improperly influence witnesses and confidential sources, fabricate testimony, and engage in other activities that could compromise the investigation. In addition, providing an individual with access to these records may reveal the identity of a source who furnished information under an express promise that their identity would remain confidential. Allowing the subject of the investigation to amend records in this system of records could likewise interfere with ongoing law enforcement proceedings and impose an impossible administrative burden by requiring law enforcement investigations to be continuously reinvestigated.

(4) From subsection (e)(1) (Relevancy and Necessity of Information) and (5) (Accuracy, Timeliness, Relevance, and Completeness), because in the course of investigations into potential violations of law, the significance of certain information may not be clear or the information may not be strictly relevant or necessary to a specific investigation; but, effective law enforcement requires the retention of all information that may aid in establishing patterns of unlawful activity and providing investigative leads.

(5) From subsection (e)(2) (Collect from Individual), because in a law enforcement investigation the requirement that information be collected to the greatest extent possible from the subject individual would present a serious impediment to law enforcement, in that the subject of the investigation would be informed of the existence of the investigation and would therefore be able to avoid detection, apprehension, or legal obligations or duties.

(6) From subsection (e)(3) (Privacy Act Statement), because to comply with the requirements of this subsection during the course of an investigation could impede the information gathering process and hamper the investigation.

(7) From subsection (e)(4)(G), (H), and (I) (Agency Requirements) and (f) (Agency Rules), because the Commission is not required to establish requirements, rules, or procedures related to access and amendment of records in a system of records that is exempt from the individual access and amendment provisions in subsection (d) of the Privacy Act.

(8) From subsection (e)(8) (Serve Notice), because the application of this provision could prematurely reveal an ongoing criminal investigation to the subject of the investigation, present a serious impediment to law enforcement by interfering with the ability to issue subpoenas or otherwise gather information, and reveal investigative techniques, procedures, or evidence.

(9) From subsection (g) (Civil Remedies), because this system of records is exempt from the individual access and amendment provisions in subsection (d) of the Privacy Act for the reasons noted in paragraph (e)(3) of this section; therefore, the Commission is not subject to civil action for failure to adhere to those requirements.

(f) *CFTC–44 Personnel Clearance System.* The system of records identified as CFTC–44 Personnel Clearance System contains records related to the background investigations and security clearances of individuals who have been or are being considered for access to Commission facilities, information technology systems, and classified or confidential information. These records may include statements from individuals who have provided information in the course of a background investigation and have requested that their identity remain confidential. Pursuant to 5 U.S.C. 552a(k)(2) and (k)(5) and subject to the requirements and limitations set forth therein, the Commission is exempting this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f), and from the following corresponding sections of this part: 146.3; 146.5; 146.6(d); 146.11(a)(7), (8), and (9); and 146.7(a). Exemptions from these particular subsections of the Privacy Act are justified for the following reasons:

(1) From subsections (c)(3) (Accounting of Certain Disclosures), because release of the accounting of certain disclosures could alert the subject of an investigation to the extent of that investigation and reveal investigative interests of the Commission and the recipient entity that were previously unknown to the individual. Release of such information to the subject of an investigation could reasonably be anticipated to impede and interfere with the Commission's efforts to adequately assess an individual when making a decision about the individual's access to Commission facilities, information technology systems, and classified and confidential information.

(2) From subsection (d)(1), (2), (3), and (4) (Access and Amendment), because the records contained in this system may be related to ongoing investigations, and individual access to these records could alert the subject of an investigation to the extent of that investigation and reveal investigative interests of the Commission and others that were previously unknown to the

individual. Providing a subject with access to these records could impair the effectiveness of the Commission's investigations and could significantly impede the investigation by providing the opportunity for the subject to destroy documentary evidence, improperly influence witnesses and confidential sources, fabricate testimony, and engage in other activities that could compromise the investigation. In addition, providing an individual with access to these records may reveal the identity of a source who furnished information under an express promise that their identity would remain confidential. Amendment of the records in this system of records would interfere with ongoing law enforcement proceedings and impose an impossible administrative burden by requiring law enforcement investigations to be continuously reinvestigated.

(3) From subsection (e)(1) (Relevancy and Necessity of Information), because in the course of conducting and adjudicating background investigations, the significance of certain information may not be clear or the information may not be strictly relevant or necessary to a specific investigation; but, effective investigations require the retention of all information that may aid in the investigation and provide investigative leads.

(4) From subsection (e)(4)(G), (H), and (I) (Agency Requirements) and (f) (Agency Rules), because the Commission is not required to establish requirements, rules, or procedures related to access and amendment of records in a system of records that is exempt from the individual access and amendment provisions in subsection (d) of the Privacy Act.

(g) *CFTC–49 Whistleblower Records.* The system of records identified as CFTC–49 Whistleblower Records contains records related to whistleblower tips, complaints and referrals, records related to investigations and inquiries into whistleblower complaints, and records related to the whistleblower award claim and determination process. Pursuant to 5 U.S.C. 552a(k)(2) and subject to the requirements and limitations set forth therein, the Commission is exempting this system of records from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3); (d)(1), (2), (3), and (4); (e)(1); (e)(4)(G), (H), and (I); and (f), and from the following corresponding sections of this part: 146.3; 146.5; 146.6(d); 146.11(a)(7), (8), and (9); and 146.7(a). Exemptions from these particular subsections of the Privacy Act are justified for the following reasons:

(1) From subsection (c)(3) (Accounting of Certain Disclosures), because release of the accounting of certain disclosures could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and the recipient entity. Release of such information to the subject of an investigation could reasonably be anticipated to impede and interfere with the Commission's efforts to identify and investigate unlawful activities.

(2) From subsection (d)(1), (2), (3), and (4) (Access and Amendment), because individual access to these records could alert the subject of an investigation to the existence and extent of that investigation and reveal the investigative interests of the Commission and others. Providing a subject with access to these records could impair the effectiveness of the Commission's investigations and could significantly impede the investigation by providing the opportunity for the subject to destroy documentary evidence, improperly influence witnesses and confidential sources, fabricate testimony, and engage in other activities that could compromise the investigation. Allowing the subject of the investigation to amend records in this system of records could likewise interfere with ongoing law enforcement proceedings and impose an impossible administrative burden by requiring law enforcement investigations to be continuously reinvestigated.

(3) From subsection (e)(1) (Relevancy and Necessity of Information), because in the course of investigations, the significance of certain information may not be clear or the information may not be strictly relevant or necessary to a specific investigation; but, effective investigations require the retention of all information that may aid in the investigation or aid in establishing patterns of activity and provide investigative leads.

(4) From subsection (e)(4)(G), (H), and (I) (Agency Requirements) and (f) (Agency Rules), because the Commission is not required to establish requirements, rules, or procedures related to access and amendment of records in a system of records that is exempt from the individual access and amendment provisions in subsection (d) of the Privacy Act.

§ 146.13 [Removed]

■ 3. Remove § 146.13.

Issued in Washington, DC, on January 24, 2024, by the Commission.

Christopher Kirkpatrick,

Secretary of the Commission.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Privacy Act Regulations—Commission Voting Summary

On this matter, Chairman Behnam and Commissioners Johnson, Goldsmith Romero, Mersinger, and Pham voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2024–01684 Filed 2–1–24; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2016–D–2343]

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a revised draft Introduction, and a revised draft Appendix 1, within a multichapter guidance for industry entitled ''Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' This multichapter draft guidance, when finalized, will explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under our rule entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.'' We revised the draft Introduction and draft Appendix 1: Known or Reasonably Foreseeable Hazards (''Potential Hazards'') to address comments submitted on drafts that we made available in 2016. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by June 3, 2024 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–2016–D–2343 for ''Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' 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 guidance to the Office of Food Safety (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Linda Kahl, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2784.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised draft Introduction and a revised draft Appendix 1 of a multichapter draft guidance for industry entitled ''Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' We previously announced the availability of several chapters of that draft guidance as shown in table 1.

TABLE 1—AVAILABLE DRAFT CHAPTERS IN HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Chapter No.	Chapter title	Publication
N/A	Introduction	81 FR 57816, August 24, 2016.
1	The Food Safety Plan	81 FR 57816, August 24, 2016.
2	Conducting a Hazard Analysis	81 FR 57816, August 24, 2016.
3	Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food.	81 FR 57816, August 24, 2016.
4	Preventive Controls	81 FR 57816, August 24, 2016.
5	Application of Preventive Controls and Preventive Control Management Components.	81 FR 57816, August 24, 2016.
6	Use of Heat Treatments as a Process Control	82 FR 41364, August 31, 2017.
11	Food Allergen Program	88 FR 66457, September 27, 2023.
14	Recall plan	84 FR 53347, October 7, 2019.
15	Supply-Chain Program for Human Food Products	83 FR 3449, January 25, 2018.
16	Acidified Foods	88 FR 66457, September 27, 2023.
Appendix 1	Potential Hazards for Foods and Processes	81 FR 57816, August 24, 2016.
Appendix 2	Food Safety Plan Forms	81 FR 57816, August 24, 2016.
Appendix 3	Bacterial Pathogen Growth and Inactivation	81 FR 57816, August 24, 2016.

We are issuing these revised sections of the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities under our regulations in 21 CFR part 1, subpart H, in accordance with section 415 of the FD&C Act (21 U.S.C. 350d). We have established regulations to implement these requirements within part 117 (21 CFR part 117).

The multichapter draft guidance for industry is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under part 117, principally in subparts C and G. One revised draft that we are announcing in this document is ''Introduction and General Information Applicable to This Guidance.'' We revised the draft Introduction that we made available in 2016 to address comments submitted regarding the draft Introduction, include all draft definitions that we subsequently included in chapters we have made available, and add draft recommendations for training applicable to most topics covered in the multichapter guidance. We also added two administrative features. One feature is a comprehensive bibliography of references that we cited within the chapters previously made available, as well as references that we expect to cite in the additional chapters that we have included in the table of contents. Another feature is a compilation of resources that could be useful to persons who use the multichapter guidance.

The second revised draft that we are announcing in this document is ''Appendix 1: Known or Reasonably Foreseeable Hazards (''Potential Hazards'').'' We revised the draft Appendix 1 that we made available in 2016 to add text providing context for what the Appendix is, how it was developed, and how it should be used. To address comments submitted regarding the draft Appendix, we made several changes, including: (1) significantly revised product categories (which emphasize ingredients that go into foods rather than finished foods that can be formulated with many variations of such ingredients); (2) replaced a series of tables listing known or reasonably foreseeable (''potential'') process-related hazards with a discussion of such hazards; (3) provided a general discussion of food allergen hazards rather than identify known or reasonably foreseeable (''potential'') food allergen hazards that could apply to multiple product categories; and (4) identified scientific, technical, or regulatory information that we considered when identifying some hazards that are known or reasonably foreseeable (''potential''), but less common, hazards in some food categories.

We intend to announce the availability for public comment of additional chapters of the draft guidance as we complete them. The titles of the additional chapters that we expect to make available for public comment are included in the table of contents for the complete multichapter guidance.

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 part 117 have been approved under OMB control number 0910–0751.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/FoodGuidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: January 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01911 Filed 1–30–24; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED–2023–OPE–0123]

Negotiated Rulemaking Committee; Announcement of Fourth Session of Committee Meetings—Title IV Federal Student Aid Programs, Student Debt Relief

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice of intent to establish negotiated rulemaking committee; amendment.

SUMMARY: On August 31, 2023, we announced our intention to establish the Student Debt Relief Negotiated Rulemaking Committee (Committee) to develop proposed regulations related to the modification, waiver, release, or compromise of Federal student loans under the Higher Education Act of 1965, as amended (HEA). We now announce a fourth session of Committee negotiations on February 22 and 23, 2024.

DATES: The dates, times, and location of the fourth Committee meeting are set out in the *Amended Schedule for Negotiation Sessions* section under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: For information about the content of this document, including information about the negotiated rulemaking process or the schedule for negotiations, please contact Rene Tiongquico. Telephone: (202) 453–7513. Email: *rene.tiongquico@ed.gov.*

For information about negotiated rulemaking, see ''The Negotiated Rulemaking Process for Title IV Regulations—Frequently Asked Questions'' at *https://www2.ed.gov/policy/highered/reg/hearulemaking/hea08/neg-reg-faq.html.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION: On August 31, 2023, we published in the **Federal Register** (88 FR 60163) an announcement of our intent to establish the Committee under section 492 of the HEA to develop proposed regulations related to section 432(a) of the HEA, which relate to the modification, waiver, or compromise of Federal

student loans by the Department. In that announcement, we set a schedule for Committee meetings and requested nominations for individual negotiators who represent key stakeholder constituencies for the issue to be negotiated to serve on the Committee. The Committee met on October 10–11, November 6–7, and December 11–12, 2023. During the negotiation sessions, the Committee discussed proposed regulations presented by the Department. At the end of the third negotiation session, the Committee took final consensus checks on each of the proposed regulations presented by the Department. In addition to the proposed regulations presented by the Department, the Committee discussed whether and how the Department could identify borrowers who are facing hardship but whose situations may not be reflected in either existing regulations or in the proposed regulations considered by the Committee.

Based upon a continued review of information related to hardship, the Department will convene the Committee for a fourth session to discuss only proposed regulations relating to that issue. The Committee will not discuss the proposed regulations for which it already conducted final consensus checks.

Amended Schedule for Negotiation Sessions: The Committee will meet for a fourth session on February 22–23, 2024.

Session times will be from 10 a.m. to 12 p.m. and 1 p.m. to 4 p.m., with a public comment period from approximately 3 p.m. to 4 p.m., Eastern time on February 22, 2024. The Department will hold public comment only on February 22, 2024.

This session will be conducted virtually and available for the public to view. Individuals who wish to observe the Committee meetings must register. We will post a registration link closer to the start of negotiations on our website at *www2.ed.gov/policy/highered/reg/hearulemaking/2023/index.html.* The Department will also post recordings and transcripts of the meetings on that site.

We will provide information on how to request time to speak on our website at *www2.ed.gov/policy/highered/reg/hearulemaking/2023/index.html.*

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access the documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1098a.

Nasser H. Paydar,

Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 2024–02107 Filed 2–1–24; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0494; FRL–9931–01–R9]

Air Plan Approval; Nevada; Clark County Department of Environment and Sustainability; Nonattainment New Source Review; 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of Nevada addressing the nonattainment new source review (NNSR) requirements for the 2015 ozone National Ambient Air Quality Standards (NAAQS). This SIP revision addresses the Clark County Department of Environment and Sustainability (DES or ''Department'') portion of the Nevada SIP. This action is being taken pursuant to the Clean Air Act (CAA or ''Act'') and its implementing regulations.

DATES: Comments must be received on or before March 4, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2022–0494, at *https://www.regulations.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets*. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Amita Muralidharan, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4140 or by email at *muralidharan.amita@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. Background and Purpose

On October 26, 2015, the EPA promulgated a revised ozone NAAQS of 0.070 parts per million (ppm).[1] Upon promulgation of a new or revised NAAQS, the CAA requires the EPA to designate as nonattainment any area that is violating the NAAQS based on the three most recent years of ambient

[1] 80 FR 65292 (October 26, 2015).

air quality data. This action relates to Clark County, which was designated nonattainment for the 2015 ozone NAAQS on June 4, 2018.[2] Within Clark County, the Las Vegas Valley [3] was classified as a ''Marginal'' ozone nonattainment area for the 2015 ozone NAAQS. On January 5, 2023, the area was reclassified by operation of law to a ''Moderate'' ozone nonattainment area for failing to attain the 2015 ozone NAAQS by the applicable attainment date.[4] However, because the Department certified that its SIP-approved NNSR program satisfies the requirements for a Marginal area only, this action is only proposing to approve the Department's certification as it pertains to a Marginal ozone nonattainment area.

On December 6, 2018, the EPA issued a final rule entitled, ''Implementation of the 2015 National Ambient Air Quality Standards for Ozone: Nonattainment Area State Implementation Plan Requirements,'' (''2015 SIP Requirements Rule'') which establishes the requirements and deadlines that state, tribal, and local air quality management agencies must meet as they develop implementation plans for areas where ozone concentrations exceed the 2015 ozone NAAQS.[5] Based on the initial nonattainment designation for the 2015 ozone standards, the Department was required to make a SIP revision addressing NNSR no later than August 3, 2021.[6] This requirement may be met by submitting a SIP revision consisting of a new or revised NNSR permit program, or an analysis demonstrating that the existing SIP-approved NNSR permit program meets the applicable 2015 ozone requirements and a letter certifying the analysis.

II. The State's Submittal

A. What did the State submit?

The submitted 2015 Ozone Certification letter addressed by this proposal was adopted by the Department on July 20, 2021. It was submitted by the Nevada Division of Environmental Protection (NDEP), the agency that serves as the governor's designee for Nevada SIP submittals, on August 5, 2021, by a letter dated August 3, 2021.

NDEP's August 5, 2021 submittal of the Clark County DES 2015 Ozone Certification letter was deemed by operation of law to meet the completeness criteria in 40 CFR part 51, Appendix V on February 5, 2022, which must be met before formal EPA review.

B. What is the purpose of the submitted certification letter?

The Department's submittal is intended to satisfy the 2015 SIP Requirements Rule that requires States to make a SIP revision addressing NNSR. The Department's portion of the Nevada SIP currently contains its NNSR permit program that was approved in 2014, prior to the Las Vegas Valley's current ozone nonattainment designation.[7] The submitted certification letter provides a mechanism for the Department to satisfy the 40 CFR 51.1314 submittal requirements based on its 2015 Marginal ozone nonattainment designation. The EPA's analysis of how this SIP revision addresses the NNSR requirements for the 2015 ozone NAAQS is provided below.

III. Analysis of Nonattainment New Source Review Requirements

NNSR is a preconstruction review permit program that applies to new major stationary sources or major modifications at existing sources within a nonattainment area and is required under CAA sections 172(c)(5) and 173.

As mentioned in Section I of this notice, NNSR permit program requirements were adopted for the 2015 ozone NAAQS at 40 CFR 51.1314 as part of the 2015 SIP Requirements Rule.[8] The minimum SIP requirements for NNSR permitting programs for the 2015 ozone NAAQS are contained in 40 CFR 51.165. These NNSR program requirements include those promulgated in the 2015 SIP Requirements Rule implementing the 2015 ozone NAAQS. The SIP for each ozone nonattainment area must contain NNSR provisions that: (1) set major source thresholds for nitrogen oxides (NO_X) and volatile organic compounds (VOC) pursuant to 40 CFR 51.165(a)(1)(iv)(A)(*1*)(*i*)–(*iv*) and (*2*); (2) classify physical changes as a major source if the change would constitute a major source by itself pursuant to 40 CFR 51.165(a)(1)(iv)(A)(*3*); (3) consider any significant net emissions increase of NO_X as a significant net emissions increase for ozone pursuant to 40 CFR 51.165(a)(1)(v)(E); (4) consider any increase of VOC emissions in Extreme ozone nonattainment areas as a significant net emissions increase and a major modification for ozone pursuant to 40 CFR 51.165(a)(1)(v)(F); (5) set significant emissions rates for VOC and NO_X as ozone precursors pursuant to 40 CFR 51.165(a)(1)(x)(A)–(C) and (E); (6) contain provisions for emissions reductions credits pursuant to 40 CFR 51.165(a)(3)(ii)(C)(*1*)–(*2*); (7) provide that the requirements applicable to VOC also apply to NO_X pursuant to 40 CFR 51.165(a)(8); (8) set offset ratios for VOC and NO_X pursuant to 40 CFR 51.165(a)(9)(ii)–(iv); and (9) require public participation procedures compliant with 40 CFR 51.165(i).

The Department's SIP-approved NNSR program,[9] established in Section 12.3 of the Clark County Air Quality Regulations, applies to the construction and modification of stationary sources, including major stationary sources in nonattainment areas under its jurisdiction. The Department's submitted SIP revision includes a compliance demonstration, consisting of a table listing each of the 2015 ozone NAAQS NNSR SIP requirements from 40 CFR 51.165 and a citation to the specific provision of the rule satisfying the requirement. The submittal also includes a certification by the Department that the cited rules meet the federal NNSR requirements for the Marginal ozone nonattainment designation. These documents, including our Summary of Evaluation [10] of the Department's submittal, are available in the docket for this action.

The EPA has reviewed the demonstration and cited program elements intended to meet the federal NNSR requirements for the 2015 ozone NAAQS and is proposing to approve the Department's submittal because the current SIP-approved NNSR program satisfies all the 2015 SIP Requirements Rule NNSR program requirements applicable to the Las Vegas Valley as a Marginal ozone nonattainment area.

IV. Proposed Action and Public Comment

The EPA is proposing to approve a SIP revision addressing the NNSR requirements for the 2015 ozone

[2] 83 FR 25776 (June 4, 2018).

[3] The Las Vegas Valley is the portion of Clark County referred to as Hydrographic Area 212. Hydrographic areas are shown on the State of Nevada Division of Water Resources' map titled ''Water Resources and Inter-basin Flows'' (September 1971).

[4] 88 FR 775 (January 5, 2023).

[5] 83 FR 62998 (December 6, 2018). The 2015 SIP Requirements Rule addresses a range of nonattainment area SIP requirements for the 2015 ozone NAAQS, including requirements pertaining to attainment demonstrations, reasonable further progress (RFP), reasonably available control technology, reasonably available control measures, major new source review, emission inventories, and the timing of SIP submissions and of compliance with emission control measures in the SIP.

[6] 40 CFR 51.1314.

[7] 79 FR 62350 (October 17, 2014).

[8] 83 FR 62998 (December 6, 2018).

[9] 79 FR 62350 (October 17, 2014).

[10] Our review of the Department's submittal is included in a Memorandum to Docket EPA–R09–OAR–2022–0494, titled ''EPA Summary of Evaluation—Clark County Department of Environment and Sustainability 2021 Ozone Certification,'' dated November 28, 2023.

NAAQS for the Department. In support of this proposed action, we have concluded that our approval of the submitted 2015 ozone certification for the Department would comply with section 110(l) of the Act because our approval of the ozone certification will not interfere with continued attainment or maintenance of the NAAQS in the Department. Similarly, we find that the submitted revision is approvable under section 193 of the Act because it does not modify any control requirement in effect before November 15, 1990, without ensuring equivalent or greater emission reductions. The EPA has concluded that the State's submission fulfills the 40 CFR 51.1314 revision requirement and meets the requirements of CAA sections 110, 172(c)(5), 173, 182(a)(2)(C), 193, and the minimum SIP requirements of 40 CFR 51.165. If we finalize this action as proposed, our action will incorporate this certification into the federally enforceable SIP and be codified through revisions to 40 CFR 52.1470 (Identification of plan).

The EPA has made, and will continue to make, the State's submission and all other materials available electronically through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). We will accept comments from the public on this proposal until March 4, 2024.

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it proposes to approve a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The State did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: January 29, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2024–02088 Filed 2–1–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0626; FRL–11614–01–R9]

Air Plan Disapproval; California; Los Angeles-South Coast Air Basin; 1997 8-Hour Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to disapprove a state implementation plan (SIP) revision submitted by the State of California to meet a Clean Air Act (CAA) requirement for the 1997 8-hour ozone national ambient air quality standards (NAAQS or ''standards'') in the Los Angeles-South Coast Air Basin, California ozone nonattainment area (''South Coast''). This submission, titled ''Final Contingency Measure Plan—Planning for Attainment of the 1997 80 ppb 8-hour Ozone Standard in the South Coast Air Basin,'' (''Contingency Measure Plan'' or ''Plan''), addresses the CAA requirements for the submission of contingency measures that will be implemented if emissions reductions from anticipated technologies associated with the area's 1997 ozone NAAQS attainment demonstration are not achieved. We are taking comments on this proposal and plan to follow with a final action.

DATES: Comments must be received on or before March 4, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2023–0626 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3964 or by email at *vagenas.ginger@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

Table of Contents

I. Background

A. Ozone Standards, Area Designations, and State Implementation Plans

Ground-level ozone pollution is formed from the reaction of volatile organic compounds (VOC) and oxides of nitrogen (NO_X) in the presence of sunlight.[1] These two pollutants, referred to as ozone precursors, are emitted by many types of sources, including on-road and nonroad motor vehicles and engines,[2] power plants and industrial facilities, and smaller area sources such as lawn and garden equipment and paints.

Scientific evidence indicates that adverse public health effects occur following exposure to ozone, particularly in children and adults with lung disease. Breathing air containing ozone can reduce lung function and inflame airways, which can increase respiratory symptoms and aggravate asthma or other lung diseases.[3]

Under section 109 of the CAA, the EPA promulgates NAAQS for pervasive air pollutants, such as ozone. The NAAQS establish concentration levels whose attainment and maintenance the EPA has determined to be requisite to protect public health and welfare. In 1979, the EPA established primary (public health-based) and secondary (welfare-based) NAAQS for ozone at 0.12 parts per million (ppm) averaged over a 1-hour timeframe (''1-hour ozone NAAQS'').[4] In 1997, the EPA revised the primary and secondary ozone NAAQS to set the acceptable level of ozone in the ambient air at 0.08 ppm averaged over an 8-hour timeframe (''1997 ozone NAAQS'').[5] The EPA further tightened the 8-hour ozone NAAQS to 0.075 ppm in 2008 (''2008 ozone NAAQS''),[6] and to 0.070 ppm in 2015 (''2015 ozone NAAQS'').[7] The EPA subsequently revoked the 1-hour ozone NAAQS [8] and the 1997 ozone NAAQS,[9] but has retained applicable requirements for anti-backsliding purposes for areas that remained designated as nonattainment for those standards at the time of revocation.[10]

Section 110 of the CAA requires states to develop and submit SIPs to implement, maintain, and enforce the NAAQS. States with nonattainment areas are required to submit revisions to their SIPs that include a control strategy and technical analysis to demonstrate how the area will attain the NAAQS by the applicable attainment date (referred to as an ''attainment demonstration''), and to meet other requirements according to each area's nonattainment classification. Under CAA section 181, the EPA classifies ozone nonattainment areas as ''Marginal,'' ''Moderate,'' ''Serious,'' ''Severe,'' or ''Extreme.''

The SIP revision that is the subject of this proposed action was submitted to address the contingency measures requirement of CAA section 182(e)(5) for the 1997 ozone NAAQS. Under this provision, states relying on the development of new control techniques or improvement of existing technologies (''new technology measures'') to demonstrate attainment in an Extreme nonattainment area must submit contingency measures to the EPA that will be implemented if the anticipated new technology measures do not achieve the planned reductions.[11]

B. The South Coast Ozone Nonattainment Area

The South Coast nonattainment area for the 1997 ozone NAAQS consists of Orange County, the southwestern two-thirds of Los Angeles County, southwestern San Bernardino County, and western Riverside County. The South Coast encompasses an area of approximately 6,600 square miles and is bounded by the Pacific Ocean to the west and by the San Gabriel, San Bernardino, and San Jacinto mountains to the north and east.[12] The population of the South Coast is over 17 million people.[13]

The EPA has classified the South Coast as an ''Extreme'' nonattainment area for the 1-hour ozone NAAQS, 1997 ozone NAAQS, 2008 ozone NAAQS,

[1] The State of California refers to ''reactive organic gases'' (ROG) rather than VOC in some of its ozone-related SIP submissions. As a practical matter, ROG and VOC refer to the same set of chemical constituents, and for the sake of simplicity, we refer to this set of gases as VOC in this proposed rule.

[2] The EPA's definition of ''nonroad engine'' is found at 40 CFR 1068.30. The State of California uses the term ''off-road'' instead of ''nonroad.'' The terms are interchangeable.

[3] ''Fact Sheet—Final Revisions to the National Ambient Air Quality Standards for Ozone,'' dated March 2008, available at *https://www.epa.gov/sites/default/files/2015-08/documents/ozone_fact_sheet.pdf.*

[4] 44 FR 8202 (February 8, 1979).

[5] 62 FR 38856 (July 18, 1997).

[6] 73 FR 16436 (March 27, 2008)

[7] 80 FR 65292 (October 26, 2015).

[8] 70 FR 44470 (August 3, 2005).

[9] 80 FR 12264 (March 6, 2015).

[10] 40 CFR 51.1100(o). Continuing applicable requirements for the 1997 ozone NAAQS include the contingency measures requirement of CAA section 182(e)(5). Id. at 51.1100(o)(16); see also id. at 51.1105.

[11] The CAA section 182(e)(5) requirements are discussed in more detail in Section I.C. of this document.

[12] For a precise definition of the boundaries of the South Coast 1997 ozone nonattainment area, see 40 CFR 81.305.

[13] 2016 South Coast Ozone SIP (''2016 AQMP''), p. 1–5.

and 2015 ozone NAAQS. For the 1997 ozone NAAQS, the area has an attainment date of June 15, 2024.[14]

California first addressed the planning requirements for the 1997 ozone NAAQS with the ''Final 2007 Air Quality Management Plan'' (''2007 South Coast AQMP''), prepared by the South Coast Air Quality Management District (SCAQMD), and the ''State Strategy for California's 2007 State Implementation Plan'' (''2007 State Strategy''), prepared by the California Air Resources Board (CARB). These submittals were subsequently revised in 2009 and 2011.[15] Collectively, we refer to these submittals and revisions as the ''2007 South Coast Ozone SIP.'' CARB subsequently submitted revisions to the 2007 South Coast Ozone SIP's control strategy and commitments for the 1997 ozone NAAQS in 2012 (''2012 AQMP'') [16] and 2016 (''2016 South Coast Ozone SIP,'' including the ''2016 AQMP'').[17]

C. Clean Air Act Provisions for New Technologies

For ozone nonattainment areas classified as Extreme, the CAA recognizes that an attainment plan may rely to a certain extent on new or evolving technologies, given the long time period between developing the initial plan and attaining the standards, and the amount of emissions reductions needed to attain. CAA section 182(e)(5) authorizes the EPA to approve provisions in an Extreme area plan that anticipate development of new technology measures, and to approve an attainment demonstration based on such provisions, if the state demonstrates that: (1) such provisions are not necessary to achieve the incremental emission reductions required during the first 10 years after the area's nonattainment designation; [18] and (2) the state has submitted enforceable commitments to develop and adopt contingency measures to be implemented if the anticipated technologies do not achieve the planned reductions (''182(e)(5) contingency measures'').[19] New technology measures may include those that anticipate future technological developments as well as those that require complex analyses, decision making, and coordination among a number of government agencies.[20] An attainment demonstration that relies on planned reductions from new technology measures under section 182(e)(5) must identify the measures for which additional time would be needed for development and adoption. The plan must also show that the new technology measures cannot be fully developed and adopted by the submittal date for the attainment demonstration and must contain a schedule outlining the steps leading to final development and adoption of the measures.[21]

The state must submit the required 182(e)(5) contingency measures to the EPA no later than 3 years before proposed implementation of the plan provisions that anticipate development of new technology measures. The EPA approves or disapproves section 182(e)(5) contingency measures in accordance with CAA section 110. The contingency measures must be adequate to produce emissions reductions sufficient, in conjunction with other approved plan provisions, to make reasonable further progress (RFP) and to attain by the applicable dates. If the EPA later determines that the Extreme area has failed to make RFP or to attain, and that such failure is due in whole or part to an inability to fully implement the new technology measures approved under CAA section 182(e)(5), the EPA will require the state to implement the contingency measures to the extent necessary to assure compliance with the applicable requirement.[22]

D. The EPA's Prior Approvals of New Technology Provisions for the 1997 8-Hour Ozone Standards

In our action on the South Coast attainment demonstration for the 1997 ozone NAAQS in the 2007 South Coast Ozone SIP, the EPA approved a number of commitments regarding the development of new pollution control measures by CARB and the SCAQMD. These included CARB's commitments to achieve, by 2023, 141 tons per day (tpd) of NO_X reductions and 54 tpd of VOC reductions from defined measures and to achieve 241 tpd of NO_X reductions and 40 tpd of VOC reductions from new technology measures.[23] We also approved CARB's commitment to provide 182(e)(5) contingency measures to cover any new technology measures shortfall as part of our approval of the 2007 South Coast Ozone SIP.[24]

The 2012 AQMP included a list of proposed new technology measures intended to provide the emissions reductions necessary to attain both the 1-hour ozone standard and the 1997 8-hour ozone standard.[25] We approved these measures both for purposes of the 1-hour ozone attainment demonstration and as an update to the 2007 South Coast Ozone SIP's new technology measures for the 1997 8-hour ozone standard.[26]

In the 2016 South Coast Ozone SIP, which included an updated control strategy and attainment demonstration for the 1997 ozone standards, CARB provided a revised list of new technology measures and revised the amount of reductions needed from defined measures and new technology measures. CARB committed to achieving aggregate emissions reductions of 113 tpd of NO_X and 50 to

[14] The EPA initially designated and classified the South Coast as a ''Severe-17'' nonattainment area for the 1997 ozone NAAQS in 2004. 69 FR 23858 (April 30, 2004). We later granted CARB's request to reclassify the area to Extreme. 75 FR 24409 (May 5, 2010).

[15] 77 FR 12674 (March 1, 2012). These submittals and the related materials are included in the associated docket, available at *https://www.regulations.gov/docket/EPA-R09-OAR-2011-0622*.

[16] See 79 FR 52526 (September 3, 2014). The 2012 AQMP and related materials are included in the associated docket, available at *https://www.regulations.gov/docket/EPA-R09-OAR-2014-0185*.

[17] See 84 FR 52005 (October 1, 2019). The 2016 AQMP and related materials are included in the associated docket, available at *https://www.regulations.gov/docket/EPA-R09-OAR-2019-0051*.

[18] CAA section 182(e)(5) specifies ''the first 10 years after November 15, 1990,'' which reflects the effective date of designation for the 1-hour ozone NAAQS. The EPA has interpreted this 10-year timeframe to run from the effective date of designation for the 1997 ozone NAAQS. 76 FR 57872, 57881, n.24.

[19] CAA section 182(e)(5). In this document, we refer to such contingency measures as ''182(e)(5) contingency measures'' to distinguish them from the contingency measures that are required under CAA sections 172(c)(9) and 182(c)(9) for a failure to make reasonable further progress (RFP) or to attain by the attainment date. Attainment and RFP contingency measures are a required element of an attainment plan submission under part D of title I of the CAA and are subject to the same submittal deadline as the attainment plan. A state relying on new technology measures in an Extreme area attainment plan must submit 182(e)(5) contingency measures in addition to the attainment and RFP contingency measures otherwise required for the area. 57 FR 13498, 13524 (April 16, 1992).

[20] 57 FR 13498, 13524.

[21] Id.

[22] CAA section 182(e)(5).

[23] 77 FR 12674, 12693 (March 1, 2012). California relied on these reductions from new technology measures for the attainment demonstration, but not for the RFP demonstration or other provisions. 76 FR 57872, 57882.

[24] 77 FR 12674, 12693. See also CARB Resolution 11–22 (July 21, 2011) (CARB commitment to ''develop, adopt, and submit contingency measures by 2020 if advanced technology measures do not achieve planned reductions'') and letter dated November 18, 2011, from James N. Goldstene, Executive Officer, CARB, to Jared Blumenfeld, Regional Administrator, EPA Region IX (further clarifying CARB commitment).

[25] A list of the SCAQMD and CARB new technology measures in the 2012 AQMP is included in Table 6 of the EPA's notice of proposed rulemaking. 79 FR 29712, 29722 (May 23, 2014).

[26] 79 FR 52526, 52537 (September 3, 2014). The amount of reductions to be achieved through new technology measures for the 1997 8-hour ozone standard (40 tpd of VOC and 241 tpd of NO_X) was unchanged.

51 tpd of VOC, with 108 tpd of NO_X reductions and 41 tpd of VOC reductions coming from new technology measures, identified as ''further deployment of cleaner technologies'' addressing emissions from on-road light-duty and heavy-duty vehicles, aircraft, locomotives, ocean-going vessels, and off-road equipment.[27] We approved this updated demonstration based on CARB's previously-approved commitment to submit 182(e)(5) contingency measures by 2020 as necessary to cover any emissions reduction shortfall from new technology measures.

Because reductions from new technology measures were relied on to ensure sufficient emissions reductions by 2023 to provide for attainment of the 1997 ozone NAAQS by the June 15, 2024 attainment date, the 182(e)(5) contingency measures would be triggered upon the EPA finding that the area failed to attain and that this failure was due in whole or in part to a failure to implement provisions approved under CAA section 182(e)(5).[28]

II. Submission From the State of California

The SCAQMD prepared the Contingency Measure Plan in collaboration with CARB.[29] It was submitted by CARB to the EPA on December 31, 2019,[30] and became complete by operation of law on July 1, 2020.

The Contingency Measure Plan is intended to address the requirement in CAA section 182(e)(5) that states relying on reductions from new technology measures to demonstrate attainment must submit contingency measures no later than three years before the proposed implementation of those new technology measures.[31] Under CAA section 182(e)(5), these contingency measures are required to produce emissions reductions sufficient to make up any shortfall in reductions attributed to new technology measures that were relied upon to meet the applicable RFP or attainment requirements. In this instance, California committed to achieve the NO_X and VOC reductions necessary to attain the 1997 ozone NAAQS by 2023, relying in part on reductions from new technology measures. CARB's submittal also includes a CARB staff report titled ''South Coast 8-Hour Ozone SIP Update'' (''CARB Staff Report''), a response to public comments received on the Plan (''CARB Response to Comments''), and other supporting documents, which are included in the docket for this rulemaking action.

The Contingency Measure Plan does not include contingency measures that could be implemented in the event the area fails to attain because the previously anticipated new technologies have not achieved the planned reductions. Instead, the Plan updates the State's approach for achieving the 108 tpd of NO_X reductions that the 2016 AQMP attributed to further deployment of cleaner technologies.[32] This updated approach includes three specific strategies: (1) identified emissions reductions strategies (24–26 tpd); (2) additional incentive funding (15 tpd); and (3) federal sources and federal measures (67–69 tpd).[33]

1. Identified Emissions Reductions Strategies

Section 3 of the Contingency Measure Plan identifies NO_X reductions that exceed the anticipated reductions from defined SCAQMD measures and CARB regulations identified in the 2016 AQMP. According to the Contingency Measure Plan, by 2023, an additional 10.2–12.2 tpd of NO_X reductions would be achieved through the following: (1) RECLAIM transition rules (2 tpd); (2) facility-based mobile source measures for commercial airports (0.5 tpd); (3) facility-based mobile source measures for marine ports (3.2–5.2 tpd); (4) incentive funding (expected future funding) (1.5 tpd); and (5) Metrolink tier 4 locomotives conversion (3.0 tpd).[34]

The Plan estimates that new mobile source measures implemented by CARB would provide an additional 6.15 tpd of NO_X reductions toward the 108 tpd of NO_X reductions that the State committed to achieving through new technology measures under CAA section 182(e)(5). These measures are listed in Table 3–5 of the Plan and consist of the following: (1) low-carbon fuel standard and alternative diesel fuels regulation (1.7 tpd); (2) airborne toxic control measure (ATCM) for portable engines and the statewide portable equipment registration program (0.25 tpd); and (3) heavy duty truck inspection and maintenance program (4.2 tpd).

The Contingency Measure Plan also describes a suite of innovative measures that were not identified in the 2016 AQMP, but which had been adopted, or would soon be adopted, by CARB.[35] These measures, which the Contingency Measure Plan estimates will provide NO_X reductions of 3.0 tpd, include requirements for State contractors to use the cleanest equipment available and for State agencies to purchase the cleanest vehicles and equipment available; pricing programs to encourage people to take public transit, carpool, or walk at congested times of the day; and a measure that would require certain railroads to set aside funding for the purchase of cleaner locomotives.

As described in the Contingency Measure Plan, these reductions, in conjunction with a 4.2 tpd adjustment resulting from a previous over-commitment for reductions from ocean-going vessels,[36] will provide a total of 24–26 tpd of NO_X reductions towards the 182(e)(5) commitment.[37]

2. Additional Incentive Funding

Section 4 of the Contingency Measure Plan discusses additional incentive funding that could speed the transition to technologies that are cleaner than required by current regulations. The 2016 AQMP identified a need for over $1 billion per year in funds to incentivize the transition to clean vehicles, infrastructure, and equipment. The SCAQMD notes that in the years between the adoption of the 2016 AQMP and the adoption of the Contingency Measure Plan, its efforts to increase funding resulted in an approximate doubling of incentive funding, to $200–300 million per year.[38]

To address the shortfall between existing funding and the amount the SCAQMD estimated would be needed to adequately fund incentive measures that would provide reductions needed for attainment, the SCAQMD identifies several additional sources of funding for incentive programs and describes its ongoing advocacy efforts to secure more funding, including sponsoring

[27] 84 FR 28132 (June 17, 2019). See esp. id. at Table 7 (identifying new technology measures projected to generate 108 tpd NO_X and 41 tpd VOC emissions reductions needed by 2023).

[28] 57 FR 13498, 13524; CAA section 182(e)(5).

[29] Letter dated December 6, 2019, from Wayne Nastri, Executive Officer, SCAQMD, to Richard Corey, Executive Officer, CARB and SCAQMD Board Resolution 19–26.

[30] Letter dated December 31, 2019, from Richard W. Corey, Executive Officer, CARB, to Michael Stoker, Regional Administrator, EPA Region 9 (submitted electronically December 31, 2019).

[31] Contingency Measure Plan, p. 2.

[32] Id. at 35.

[33] Id. at 39. Although California's approved SIP relies on planned reductions from new technology measures for both NO_X and VOC emissions reductions, and the State committed to submitting contingency measures for both, the Contingency Measure Plan focuses on achieving NO_X reductions. In support of this approach, the State notes that for the 1997 ozone NAAQS the area is more sensitive to NO_X emissions reductions, and that VOC reductions from CARB's commitment will occur through implementation of the NO_X reductions strategy. Id. at 16.

[34] Id. at Table 3–1.

[35] Id. at Tables ES–1 and ES–2, and at 49–52.

[36] Id. at 47.

[37] Id. at Table ES–1.

[38] Id. at 5.

legislation that would allow the public or the SCAQMD Board to put a sales tax measure on the ballot in the South Coast region. The SCAQMD estimates this could generate a sustainable source of funding in the amount of $1.4 billion per year, and that this amount could generate 15 tpd of NO_X emissions reductions in 2023.[39]

3. Federal Sources and Federal Measures

Section 5 of the Contingency Measure Plan designates additional reductions from federal sources and measures that the SCAQMD asserts will be necessary for attainment. This section describes California's successful efforts to reduce NO_X emissions from sources subject to its regulatory authority and explains that the State has limited authority to impose emissions controls on other significant sources of emissions, such as heavy duty trucks and engines sold outside California; passenger and freight locomotives, aircraft engines, construction and agricultural equipment under 175 horsepower; and ocean-going vessels (which the Plan refers to collectively as ''federal sources'').[40] The SCAQMD notes that, while NO_X emissions in the South Coast have decreased by 70 percent since 1997, NO_X emissions from federal sources have only decreased by 15 percent over that same time period. Figure ES–3 in the Contingency Measure Plan illustrates the reductions that have been achieved since 2000 and highlights the increasing portion that federal sources contribute to the overall emissions inventory.[41]

The SCAQMD identifies the emissions reductions potential, by 2023, for the following four categories of sources under federal authority or responsibility: (1) low-NO_X heavy-duty vehicles (up to 35 tpd); (2) low-NO_X ocean-going vessels (up to 28 tpd); (3) low-NO_X locomotives (up to 11 tpd); and (4) low-NO_X aircraft (up to 4 tpd).[42]

III. The EPA's Evaluation

A. Procedural Requirements

CAA sections 110(a)(1) and (2) and section 110(l) require a state to provide reasonable public notice and an opportunity for public hearing prior to the adoption and submission of a SIP or SIP revision. To meet these procedural requirements, every SIP submission should include evidence that the state provided adequate public notice and an opportunity for a public hearing consistent with the EPA's implementing regulations in 40 CFR 51.102.

CARB's December 31, 2019 SIP submittal package includes documentation of the public processes used by the SCAQMD and CARB to adopt the Contingency Measure Plan. As documented in the SIP revision submittal package, on November 6, 2019, the SCAQMD published a notice in newspapers of general circulation in the South Coast that a public hearing to consider adoption of the Plan would be held on December 6, 2019. As documented in the Minute Order of the Air Pollution Control Board that is included in the SIP revision submittal package, the SCAQMD Governing Board adopted the Contingency Measure Plan on December 6, 2019, following the public hearing.

On November 8, 2019, CARB published on its website a notice of a public hearing to be held on December 12, 2019, to consider adoption of the plan. As evidenced by CARB Resolution 19–31, CARB adopted the Contingency Measure Plan on December 12, 2019, following a public hearing. Based on documentation included in the December 31, 2019 SIP revision submittal package, we find that both the SCAQMD and CARB have satisfied the applicable statutory and regulatory requirements for reasonable public notice and hearing prior to the adoption and submission of the Contingency Measure Plan. Therefore, we find that the submission of the Contingency Measure Plan meets the procedural requirements for public notice and hearing in CAA sections 110(a) and 110(l) and in 40 CFR 51.102.

B. Evaluation for Compliance With Clean Air Act Requirements

As described in Section I.C of this document, CAA section 182(e)(5) allows the EPA to approve an attainment demonstration for an Extreme ozone area that relies on anticipated new technology measures, if (A) the measures are not necessary to achieve emission reductions required in the first 10 years after the area's nonattainment designation, and (B) the state submits enforceable commitments to develop and adopt contingency measures to be implemented if the new technology measures do not achieve the planned reductions. The state must submit these contingency measures no later than three years before the new technology measures would be implemented.

The EPA approves or disapproves 182(e)(5) contingency measures as SIP revisions under CAA section 110. The contingency measures must be adequate to produce sufficient emission reductions, in conjunction with other provisions of the approved SIP, to allow the Extreme area to make RFP and to attain by the applicable attainment date, and must be capable of being implemented in the event of a failure to make RFP or to attain that is due in whole or part to an inability to fully implement the new technology measures approved under CAA 182(e)(5).

As recounted in Section I.C of this document, the 2007 South Coast Ozone SIP's attainment demonstration for the 1997 ozone NAAQS relied on new technology measures to achieve 241 tpd of NO_X reductions and 40 tpd of VOC reductions by 2023. With respect to the 182(e)(5) requirements, our approval of the 2007 South Coast Ozone SIP relied on CARB's commitment to ''develop, adopt, and submit contingency measures by 2020 if advanced technology measures do not achieve planned reductions.'' [43] The 2016 AQMP subsequently revised the reductions assigned to new technology measures to 108 tpd of NO_X and 41 tpd of VOC by 2023.

The Contingency Measure Plan identifies a combination of state and federal strategies that CARB and the SCAQMD project would result in the 108 tpd of NO_X reductions previously determined to be necessary for the area to attain the 1997 ozone NAAQS. As recounted in Section II of this document, these include measures identified since the 2016 AQMP that were projected to be adopted by CARB or the SCAQMD and to be implemented prior to 2023, as well as reductions anticipated from additional incentive funding included in new and anticipated state legislation, and additional reductions assigned to federal sources and measures that the State asserts will be needed to reach attainment. Thus, while some of the identified measures are enforceable and are presently being implemented to achieve reductions, others (including additional state incentive funding and federal measures) are not fully developed or implemented and are not enforceable.[44]

[39] Id. at 53–55.

[40] Id. at 56.

[41] Id. at 6.

[42] Id. at Table 5–3.

[43] 77 FR 12674, 12693. CARB's commitment is outlined in CARB Resolution 11–22 (dated July 21, 2011) and in the letter dated November 18, 2011, from James N. Goldstene, Executive Officer, CARB, to Jared Blumenfeld, Regional Administrator, EPA Region IX.

[44] For example, CARB's Response to Comments indicates that the State intends to later develop the Plan's incentive measures into SIP submittals that are ''surplus, quantifiable, permanent, and enforceable,'' and that include an enforceable mechanism to achieve the reductions from substitute projects ''if necessary,'' but that those elements were not required at the time that the Contingency Measure Plan was submitted.

Critically, while the Plan acknowledges a continuing need for additional measures to be developed and adopted to satisfy the remaining 108 tpd of NO_X projected to be necessary for the South Coast to attain the 1997 ozone NAAQS, it does not include any contingency measures that would be implemented if these anticipated measures fail to achieve the necessary reductions. This is inconsistent with CAA section 182(e)(5), which requires a state that relies on new technology measures for an Extreme area attainment demonstration to submit contingency measures that can be implemented in the event that the area fails to attain as a result of the state's inability to fully implement the new technology measures that were the basis for the EPA's approval.[45]

Additionally, the Contingency Measure Plan's assignment of NO_X reductions to federal measures and sources subject to federal authority is not approvable as a matter of law. In evaluating prior SCAQMD attainment plans that included similar ''federal assignments,'' the EPA has consistently taken the position that states do not have authority under the CAA or the U.S. Constitution to assign SIP responsibilities to the federal government.[46] For the same reasons, we see no basis for approving the federal assignments included in the Contingency Measure Plan.[47] In effect, the Contingency Measure Plan purports to shift responsibility to achieve reductions needed for the South Coast to attain the 1997 ozone NAAQS from the State to the federal government, while failing to include any contingency measures that could be implemented if the planned reductions from new technology measures are not achieved. This approach falls short of CARB's specific enforceable commitment to develop, adopt, and submit by 2020 contingency measures to be implemented if new technology measures do not achieve the planned emissions reductions, as well as the statutory requirement for CARB to submit contingency measures adequate to produce emission reductions sufficient, in conjunction with other approved plan provisions, to achieve the emission reductions necessary for attainment.

For the reasons outlined herein, we are proposing to determine that the Contingency Measure Plan does not fulfill the contingency measure requirements of CAA 182(e)(5), and on that basis to disapprove the Plan.[48]

IV. The EPA's Proposed Action and Public Comment

As authorized in section 110(k)(3) of the CAA, we are proposing full disapproval of the Contingency Measure Plan, because it fails to provide contingency measures as required by CAA section 182(e)(5), and because it relies on improper ''federal assignments'' to achieve the necessary reductions. If we finalize this disapproval, CAA section 110(c) would require the EPA to promulgate a federal implementation plan within 24 months after the effective date of the final action, unless we approve subsequent SIP revisions that correct the deficiencies identified in the final approval.

In addition, final disapproval would trigger the offset sanction in CAA section 179(b)(2) 18 months after the effective date of a final disapproval, and the highway funding sanction in CAA section 179(b)(1) six months after the offset sanction is imposed. A sanction will not be imposed if the EPA determines that a subsequent SIP submission corrects the deficiencies identified in our final action before the applicable deadline.

We will accept comments from the public on the proposed disapproval for the next 30 days.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to review state choices, and approve those choices if they meet the minimum criteria of the Act. Accordingly, this action proposes to disapprove a state submittal as not meeting federal requirements, and does not impose any additional requirements beyond those imposed by state law.

Additional information about these statutes and Executive Orders can be found at *https://www2.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 proposed action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* because this proposed SIP disapproval under section 110 and subchapter I, part D of the CAA will not in-and-of itself create any new information collection burdens, but simply disapproves certain state requirements submitted for inclusion into the SIP. Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as: (1) a small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently

[45] A state would not need to submit 182(e)(5) contingency measures if it can demonstrate attainment without relying on emission reductions from future development of new technology measures. See 84 FR 52005, 52009–52010 (explaining that California was not required to submit 182(e)(5) contingency measures for the 1-hour ozone NAAQS once the State demonstrated that it was no longer relying on new technology measures for attainment). See also Contingency Measure Plan at 1–2 (''In this submittal, the State must demonstrate that the assumed reductions from future technology were already achieved, or if not, the State must submit contingency measures capable of achieving the remaining emission reductions''). Because the Contingency Measure Plan continues to rely on emissions reductions from measures requiring additional time for development and adoption, the State remains subject to the requirement to submit 182(e)(5) contingency measures.

[46] See, *e.g.,* 61 FR 10920, 10936 (March 18, 1996); 62 FR 1150, 1152 (January 8, 1997); 64 FR 1770, 1776 (January 12, 1999); 75 FR 71294, 71309 (November 22, 2010).

[47] The executive summary to the CARB Staff Report acknowledges that federal assignments are not permitted as a matter of law, and that the reductions assigned to federal sources and measures do not constitute a legally binding requirement upon the EPA. CARB Staff Report, p. 6. While we agree with this statement, we do not rely on it to reach our conclusion that the Plan as submitted fails to meet the contingency measure requirements of 182(e)(5).

[48] See also CAA section 110(l) (specifying that EPA may not approve a SIP revision that would interfere with any applicable requirement concerning attainment or any other applicable CAA requirement).

owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed action on small entities, I certify that this proposed action will not have a significant impact on a substantial number of small entities. This proposed rule does not impose any requirements or create impacts on small entities. This proposed SIP disapproval under section 110 and subchapter I, part D of the CAA will not in-and-of itself create any new requirements but simply disapproves certain state requirements submitted for inclusion into the SIP. Accordingly, it affords no opportunity for the EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rule. The fact that the CAA prescribes that various consequences (*e.g.,* higher offset requirements) may or will result from disapproval actions does not mean that the EPA either can or must conduct a regulatory flexibility analysis for this proposed action. Therefore, this proposed action will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

This proposed action contains no Federal mandates under the provisions of title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for state, local, or tribal governments or the private sector. The EPA has determined that the proposed disapproval action does not include a federal mandate that may result in estimated costs of $100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This action proposes to disapprove pre-existing requirements under state or local law and imposes no new requirements. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, result from this proposed action.

E. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires the EPA to develop an accountable process to ensure ''meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.'' This proposed action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely disapproves certain state requirements for inclusion into the SIP and does not alter the relationship or the distribution of power and responsibilities established in the CAA. Thus, Executive Order 13132 does not apply to this proposed action.

F. Executive Order 13175, Coordination With Indian Tribal Governments

This proposed action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP that the EPA is proposing to disapprove would not apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and the EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this proposed action.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This proposed action is not subject to Executive Order 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This proposed SIP disapproval under section 110 and subchapter I, part D of the CAA will not in-and-of itself create any new regulations but simply disapproves certain state requirements submitted for inclusion into the SIP.

H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

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

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs the EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. The EPA believes that this proposed action is not subject to requirements of Section 12(d) of NTTAA because application of those requirements would be inconsistent with the CAA.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Population

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) directs federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

Neither CARB nor the SCAQMD evaluated environmental justice considerations as part of this SIP submission; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an environmental justice analysis and did not consider environmental justice in

this action. Consideration of environmental justice is not required as part of this action, and there is no information in the record inconsistent with the stated goal of Executive Order 12898 of achieving environmental justice for people of color, low-income populations, and Indigenous peoples.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 29, 2024.

Martha Guzman Aceves,

Regional Administrator, Region IX.

[FR Doc. 2024–02082 Filed 2–1–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 383 and 384

[Docket No. FMCSA–2023–0115]

RIN 2126–AC46

Amendments to the Commercial Driver's License Requirements; Increased Flexibility for Testing and for Drivers After Passing the Skills Test

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: FMCSA proposes to increase flexibility for State Driver Licensing Agencies (SDLAs) and commercial driver's license (CDL) applicants by expanding applicants' ability to take a CDL skills test in a State other than their State of domicile; permitting a commercial learner's permit (CLP) holder who has passed the CDL skills test to operate a commercial motor vehicle (CMV) on public roads without having a qualified CDL holder in the passenger seat; eliminating the requirement that an applicant wait at least 14 days to take the CDL skills test following initial issuance of the CLP. The NPRM also proposes to remove the requirement that CMV drivers must have a passenger (P) endorsement to transport CMVs designed to carry passengers, including school buses, when the vehicle is being transported in a driveaway-towaway operation and the vehicle is not carrying any passengers. Additionally, FMCSA proposes to require that third-party knowledge examiners be subject to the training, certification, and record check standards currently applicable to State knowledge examiners and third-party knowledge testers be subject to the auditing and monitoring requirements now applicable to third-party skills testers. The NPRM responds to petitions for rulemaking from the American Trucking Associations (ATA) and the New Hampshire Department of Transportation (NHDOT), as discussed below. FMCSA believes these proposals would improve the efficiency and convenience of CDL issuance and improve highway safety by further ensuring the integrity of third-party CDL knowledge testing.

DATES: Comments must be received on or before April 2, 2024.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2023–0115 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/docket/FMCSA-2023-0115/document*. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.
- *Fax:* (202) 493–2251.

FOR FURTHER INFORMATION CONTACT: Patrick D. Nemons, Director, Office of Safety Programs, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 385–2400; *patrick.nemons@dot.gov*. If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION: FMCSA organizes this NPRM as follows:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this NPRM (FMCSA–2023–0115), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *https://www.regulations.gov/docket/FMCSA-2023-0115/document,* click on this NPRM, click ''Comment,'' and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act

(5 United States Code (U.S.C.) 552), CBI is exempt from public disclosure. If your comments responsive to the 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 the NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the NPRM. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Analysis Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington DC 20590–0001. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this rulemaking.

B. Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2023-0115/document* and choose the document to review. To view comments, click this NPRM, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice DOT/ALL 14 (Federal Docket Management System (FDMS)), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices.* The comments are posted without edit, and are searchable by the name of the submitter.

D. Comments on the Information Collection

Written comments and recommendations for the information collection discussed in this NPRM should be sent within 60 days of publication to *www.reginfo.gov/public/do/PRAMain.* Find this information collection by clicking the link that reads ''Currently under Review—Open for Public Comments'' or by entering Office of Management and Budget (OMB) control number 2126–0011 in the search bar and clicking on the last entry to reach the ''comment'' button.

II. Executive Summary

A. Purpose and Summary of the Regulatory Action

The purpose of the NPRM is to enhance the flexibility and efficiency of the CDL program by removing certain regulatory restrictions to allow applicants to obtain a CDL and be productively employed as a CMV driver in less time than it currently takes, without compromising safety. The NPRM also proposes measures to ensure the consistency and integrity of the administration of CDL knowledge tests provided by third-party examiners and facilitate the safe transport of empty CMVs designed to transport passengers (passenger CMVs) more efficiently. FMCSA believes the proposed changes will further address CMV driver shortages, enhance supply chain stability, and provide appropriate regulatory relief without impacting safety. In the case of CDL knowledge testing administered by third parties, the proposal would improve safety by imposing applicable training and certification standards for third-party knowledge examiners currently required for State-employed knowledge test examiners, and by imposing monitoring standards for third-party knowledge testers currently applicable to third-party skills testers. The proposed changes are summarized immediately below and further explained in Section VI., Discussion of the Proposal.

B. Summary of Major Provisions

CDL Skills Testing for Out-of-State Applicants

Section 383.79(a)(1) currently permits a State to administer the CDL skills test to an applicant domiciled in another State, provided the individual has obtained training in the State where the skills test will be administered. Such test results must be transmitted electronically directly from the testing State to the licensing State in a direct, efficient, and secure manner. The NPRM proposes to remove the requirement that an applicant must have obtained training in the testing State in order to take the CDL skills test in that State.

With the implementation of FMCSA's entry-level driver training (ELDT) regulations in February 2022, all States can be assured that the out-of-state applicant has completed the required minimum training as set forth in 49 CFR part 380, subpart F. The NPRM, by proposing to allow States discretion to provide skills testing to out-of-State applicants, regardless of the State in which training was obtained, may allow applicants to obtain a CDL sooner by scheduling the skills test in a State with shorter waiting times. Because all States administering the CDL skills test must follow the test standards and requirements set forth in 49 CFR part 383, subparts G and H, the proposal would not adversely impact safety.

CLP Holders Who Have Passed the CDL Skills Test

Pursuant to § 383.25(a)(1), CLP holders may operate a CMV on public roads and highways only for purposes of BTW training, as long as a CDL holder is physically present in the front seat of the vehicle or, in the case of a passenger CMV, directly behind or in the first row behind the driver and has the CLP holder under observation and direct supervision. The NPRM proposes an exception to this provision that would allow CLP holders who have passed the CDL skills test to operate a CMV for any reason, provided a CDL holder is physically present in the CMV, the CLP driver has passed the CDL skills test, and the driver possesses documentary evidence from the testing State that they have passed the CDL skills test.

Since the current provision was adopted in 2012, FMCSA implemented minimum ELDT requirements, set forth in 49 CFR part 380 subpart F. Once the CLP holder has passed the skills test and, thus, demonstrated their ability to safely operate a CMV, the current restriction limiting CLP holders to CMV operation only for purpose of BTW training would no longer be necessary. Because these drivers have already met all the requirements for a CDL, but have yet to pick up the CDL document from their State of domicile, their safety performance would be the same as a newly-credentialed CDL holder. Additionally, having a CDL driver accompany the CLP driver who has successfully passed all required CDL skills testing and prerequisites, provides some additional supervision that is otherwise not required for newly-credentialed CDL drivers in physical possession of the CDL document.

CLP Holders Eligible To Take the CDL Skills Test

As set forth in § 383.25(e), CLP holders are not eligible to take the CDL skills test in the first 14 days following

initial issuance of the CLP. FMCSA proposes to eliminate this restriction, which was intended to ensure CLP holders obtained BTW training prior to taking the skills test to improve their chances of passing the test on the first attempt. The restriction is no longer necessary, however, because CLP holders must now complete ELDT (theory training and BTW range and road training) before taking the skills test for a Class A or Class B CDL or the P or school bus (S) endorsement, in accordance with § 383.73(b)(11) and (e)(9).

Third-Party Knowledge Testers and Examiners

In accordance with regulatory guidance adopted on February 3, 2022, States may authorize the use of third-party knowledge examiners as long as they adhere to the CDL knowledge test standards and requirements set forth in 49 CFR part 383, subparts G and H.[1] When issuing that guidance, FMCSA noted its intention to propose regulatory requirements further clarifying the States' use of third-party knowledge examiners. This NPRM proposes those requirements, which are intended to ensure the integrity of third-party CDL knowledge testing.

First, States authorizing third-party knowledge examiners would be required to apply to those examiners the training, certification, and record check requirements currently applicable to State knowledge examiners, as set forth in § 384.228. Third-party skills examiners already certified under § 384.228 who also administer the knowledge tests would be excepted from duplicative training and record check requirements. In addition, States would be required to include third-party knowledge examiners within the scope of the auditing and monitoring provisions set forth in § 384.229, currently applicable only to third-party skills examiners. States authorizing third-party knowledge testers (*i.e.,* entities that employ third-party knowledge examiners) and examiners would be subject to the auditing and monitoring requirements for third-party skills testers and examiners, set forth in § 383.75, as applicable. Finally, the NPRM proposes to add a requirement that third-party knowledge testers or examiners administer the knowledge test only by electronic means.

Operation of Empty Passenger CMVs

The NPRM proposes to except CDL holders operating CMVs designed to carry passengers, including school buses, from having a P endorsement when the CMV is empty of passengers and the driver is transporting the CMV from the manufacturer to the distributor or in a *driveaway-towaway operation,* as defined in § 390.5T. As explained further below, FMCSA's current regulations do not require an S endorsement to operate an empty school bus. Both the S and P endorsements are intended to ensure the driver has the knowledge and skills necessary to safely transport passengers and to evacuate the CMV in case of emergency. The proposed change would therefore enhance flexibility in transporting empty passenger CMVs to distributors, dealers, purchasers, and repair facilities without compromising passenger safety.

C. Costs and Benefits

FMCSA believes these proposals would improve the efficiency and convenience of CDL issuance, provide needed flexibility for CLP holders who have demonstrated their ability to safely operate a CMV by passing the CDL skills test, improve highway safety by ensuring the integrity of third-party CDL knowledge testing, and enhance flexibility in the transport of empty passenger CMVs from the manufacturer to the distributor or in a driveaway-towaway operation. The proposed rule could affect States, third-party knowledge examiners, CDL applicants, CMV drivers, and motor carriers.

FMCSA anticipates that entities acting under the proposed flexibilities would incur cost savings via improved operational efficiency. FMCSA cannot predict the number of States that would voluntarily adopt the changes set forth in this proposal, and is therefore unable to quantify the increase in efficiency experienced by the affected entities. FMCSA estimates that the 10-year cost for training and certification of third-party knowledge examiners could total approximately $92 million on an undiscounted basis, $81 million discounted at 3 percent, and $69 million discounted at 7 percent. Annualized costs would total $9.24 million discounted at 3 percent and $9.24 million discounted at 7 percent (all in 2021 dollars).

III. Abbreviations

ANPRM Advance Notice of Proposed Rulemaking
ATA American Trucking Associations
BTW Behind-The-Wheel
CBI Confidential Business Information
CDL Commercial Driver's License
CDLIS Commercial Driver's License Information System
CE Categorical Exclusion
CFR Code of Federal Regulations
CLP Commercial Learner Permit
CMV Commercial Motor Vehicle
CMVSA Commercial Motor Vehicle Safety Act of 1986
CRST CRST Expedited
C.R. England C.R. England, Inc.
DOT Department of Transportation
ELDT Entry-Level Driver Training
E.O. Executive Order
FMCSA Federal Motor Carrier Safety Administration
FMCSR Federal Motor Carrier Safety Regulations
FR Federal Register
NAICS North American Industry Classification System
NEPA National Environmental Policy Act of 1969
NHDOT State of New Hampshire Department of Transportation
NPRM Notice of Proposed Rulemaking
OIRA Office of Information and Regulatory Affairs
OMB Office of Management and Budget
PIA Privacy Impact Assessment
PII Personally Identifiable Information
Prime New Prime, Inc.
PTA Privacy Threshold Assessment
RFA Regulatory Flexibility Act
The Secretary Secretary of Transportation
SDLA State Driver Licensing Agency
UMRA Unfunded Mandates Reform Act of 1995
U.S.C. United States Code

IV. Legal Basis for the Rulemaking

The Administrator of FMCSA is delegated authority under 49 CFR 1.87 to carry out the functions vested in the Secretary of Transportation by 49 U.S.C. chapters 311, 313, and 315 as they relate to CMV operators, programs, and safety. The NPRM is based primarily on the broad authority of the Commercial Motor Vehicle Safety Act of 1986 (CMVSA), as amended, codified at 49 U.S.C. chapter 313, which established the CDL program. The statute required the Secretary of Transportation (Secretary), after consultation with the States, to prescribe uniform minimum standards ''for testing and ensuring the fitness of an individual operating a commercial motor vehicle'' (49 U.S.C. 31305(a)(1)). The NPRM proposes to amend two of the CDL testing requirements and proposes new requirements for the administration of the CDL knowledge test by third-party testers and examiner. The NPRM also addresses the fitness of a CLP holder who has passed the CDL skills test to operate a CMV on public roads and the fitness of Class B CDL holders to operate an empty passenger CMV without obtaining the P endorsement.

The NPRM is also consistent with the concurrent authorities of the Motor Carrier Safety Act of 1984, as amended, codified at 49 U.S.C. 31131, *et seq.;* and the Motor Carrier Act of 1935, as amended, codified at 49 U.S.C. 31502. The 1984 statute granted the Secretary

[1] See, 87 FR 6045 (Feb. 3, 2022).

broad authority to issue regulations ''on commercial motor vehicle safety,'' including regulations to ensure that ''commercial motor vehicles are . . . operated safely'' (49 U.S.C. 31136(a)(1)). The NPRM is consistent with the safe operation of CMVs. In accordance with section 31136(a)(2), the enhanced flexibilities proposed in the NPRM will not impose any ''responsibilities . . . on operators of commercial motor vehicles [that would] impair their ability to operate the vehicles safely.'' This NPRM does not directly address medical standards for drivers (section 31136(a)(3)) or possible physical effects caused by driving CMVs (section 31136(a)(4)). FMCSA does not anticipate that drivers will be coerced (section 31136(a)(5)) if the NPRM results in the issuance of a final rule.

Title 49 U.S.C., section 31502(b), provides that ''The Secretary of Transportation may prescribe requirements for—(1) qualifications and maximum hours of service of employees of, and safety of operation and equipment of, a motor carrier; and (2) qualifications and maximum hours of service of employees of, and standards of equipment of, a motor private carrier, when needed to promote safety of operation.'' The NPRM, which addresses certain knowledge and skills testing requirements, is related to the safe operation of motor carrier equipment.

V. Background

On May 9, 2011, FMCSA published the CDL Testing and CLP Standards final rule (76 FR 26854) (May 2011 final rule) amending the CDL knowledge and skills testing standards and establishing new minimum Federal standards for States to issue the CLP. Each of the regulatory provisions that FMCSA proposes to revise in the NPRM, discussed below, were either adopted initially (§§ 383.25, 383.79, 384.228, and 384.229) or revised (§§ 383.5 and 383.75) in the May 2011 final rule.

On July 13, 2020, the ATA submitted a petition for rulemaking to FMCSA requesting that the Agency codify three CDL-related waivers issued (and subsequently reissued) in response to the coronavirus disease 2019 (COVID–19) pandemic:

(1) Allow third-party CDL skills test examiners the ability to administer the CDL knowledge test, so long as the examiner maintains their CDL skills test examiner certification, has successfully completed a CDL skills test examiner training course, and completes a unit devoted to administering the knowledge test as required in § 384.228(c)(3); [2]

(2) Eliminate from the requirement in § 383.25(a)(1) that a CLP holder who has passed the CDL driving skills test be accompanied by a CDL holder with the proper CDL class and endorsements, seated in the front seat of a CMV, while the CLP holder operates a CMV on public roads or highways, provided that the CLP holder possesses evidence from a testing jurisdiction (including an authorized third-party tester) that a CLP holder has passed the CDL driving skills test, and provided that the CDL holder is elsewhere in the cab; and

(3) Eliminate the restriction under § 383.79(a) limiting States to the administration of driving skills tests to CDL applicants not domiciled in the testing State only if the applicant took driver training in that State. Each of the waivers was based on the need for regulatory flexibility in response to COVID–19-related service disruptions at the SDLAs and to enhance the efficiency of the commercial licensing process so that applicants could obtain a CDL more quickly. FMCSA issued the waivers after finding that granting the regulatory relief would achieve a level of safety equal to, or greater than, the level of safety achieved in the absence of the waivers, as required by 49 U.S.C. 31315(a). The waivers, discussed further below, are available in the docket of this rulemaking and can also be accessed at *https://www.fmcsa.dot.gov/emergency/covid-19-archives.*

The ATA asserted that permanent incorporation of these temporary relief measures into the Federal Motor Carrier Safety Regulations (FMCSRs) would reduce regulatory burdens, aid the ongoing COVID–19 recovery efforts, and ''ensure continuity in the American supply chain.'' The Agency granted ATA's petition on November 24, 2021. The NPRM is based, in part, on ATA's petition for rulemaking, as discussed further below.

A. Third Party Testing (§ 383.75)

On April 9, 2020, FMCSA waived the CDL knowledge test examiner training requirements in § 384.228(b) and (c) for certain third-party CDL skills test examiners. The waiver allowed State-authorized third-party skills test examiners who have maintained a valid CDL test examiner certification and have previously completed a CDL skills test examiner training course satisfying the requirements of § 384.228(d) to administer the CDL knowledge test without completing a CDL knowledge test training course. (At the time of issuance, FMCSA's existing regulatory guidance stated that third-party knowledge testing was prohibited and that if an employee of the State authorized to supervise knowledge testing is present during the testing, FMCSA regards the test as being administered by the State and not by a third party.) The waiver allowed States and SDLAs to use third-party CDL skills test examiners to continue administering CDL knowledge tests while SDLAs remained closed, unable to administer CDL knowledge tests, or operating at a diminished capacity due to the COVID–19 emergency. The Agency reissued the waiver June 22, 2020, September 18, 2020, December 15, 2020, February 16, 2021, May 26, 2021, August 31, 2021, and November 29, 2021. As discussed below, FMCSA rescinded the waiver on February 3, 2022.

On February 3, 2022, FMCSA published a notice of regulatory guidance concerning the States' use of third parties to administer CDL knowledge tests (87 FR 6045 (Feb. 3, 2022)) (February 2022 guidance). The guidance rescinded previously issued guidance, discussed above, stating that States' use of third-party knowledge test examiners was prohibited if a State employee was not present. The February 2022 guidance affirmed that FMCSA's statutes and regulations do not prohibit States from authorizing third parties to administer CDL knowledge tests, as long as SDLAs adhere to the CDL knowledge test standards and testing requirements set forth in 49 CFR part 383, subparts G and H. Currently, FMCSA does not impose any other regulatory requirements pertaining to the States' optional use of third-party knowledge testing. In the February 2022 notice, FMCSA explained it was developing an NPRM to propose regulatory standards for third-party knowledge testing and, in the interim, encouraged States opting to use third-party knowledge examiners to follow the training, certification, and record check requirements currently applicable to State knowledge examiners. This NPRM proposes those regulatory standards. The Agency subsequently issued additional guidance recommending best practices for States that allow third-party knowledge testing, discussed further below in section VI. On February 3, 2022, FMCSA also terminated the November 29, 2021, waiver then in effect allowing States, at their discretion, to permit certified third-party skills examiners to administer the

[2] As discussed below in Section V.A., FMCSA withdrew the third-party knowledge examiner testing waiver on February 3, 2022.

CDL knowledge test, subject to certain conditions.[3] The Agency withdrew the waiver because it was based on the prior (rescinded) guidance stating that third-party knowledge testing was prohibited under FMCSA's regulations.

B. CLP Holders Who Have Passed the CDL Skills Test (§ 383.25(a))

Pursuant to § 383.325(a), a CLP is considered a valid CDL for purposes of BTW training on public roads or highways, as long as specified minimum conditions are met. One of these conditions, set forth in § 383.25(a)(1), requires that the CLP holder be accompanied by the holder of a valid CDL with the proper CDL group and endorsement(s), who is physically present in the front seat of the vehicle next to the CLP holder or, in the case of a passenger CMV, directly behind or in the first row behind the driver, and must have the CLP holder under direct observation and supervision. In adopting this provision in the May 2011 final rule, the Agency noted that it is not safe to permit inexperienced drivers who have not passed the CDL skills test to drive unaccompanied.[4]

Applications for Exemption—§ 383.25(a)(1)

On November 28, 2014, the Agency published for notice and comment C.R. England Inc.'s (C.R. England) request for an exemption from § 383.25(a)(1), which would allow CLP holders who have passed the CDL skills test and are eligible to receive a CDL to drive a truck without a CDL holder being present in the front seat, as long as the CDL holder is present elsewhere in the vehicle (79 FR 70916). FMCSA, after analyzing the exemption application and public comments received, determined that the exemption, subject to the terms and conditions imposed, would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. Subsequently, on June 11, 2015, the Agency published notice that it granted the C.R. England exemption, effective June 13, 2015, through June 12, 2017 (80 FR 33329). Under the terms and conditions of the exemption, a CLP holder who has documentation of passing the CDL skills test may drive a CMV for C.R. England without being accompanied by a CDL holder in the front seat. In granting the exemption, FMCSA concluded that CLP holders who have passed the skills test are qualified and eligible to receive a CDL. The exemption enabled CLP holders to drive as part of a team and have the same regulatory flexibility that 49 CFR 383 provides for C.R. England's team drivers with CDLs. On June 12, 2017, FMCSA published notice of its decision to grant C.R. England's request that the initial exemption be renewed for a period of 5 years, from June 13, 2017, through June 12, 2022 (82 FR 26975). The Agency subsequently renewed this exemption again for another 5 years from June 13, 2022, until June 12, 2027 (87 FR 36360). The renewals of the exemption were based, in part, on C.R. England's data demonstrating that drivers utilizing the exemption during the initial exemption period had better safety outcomes than non-exempt drivers. The Agency also requested comments on each 5-year extension. The C.R. England exemption requests and the notices of FMCSA's disposition are available in the docket for this rulemaking.

On January 5, 2016 (81 FR 291), FMCSA published notice of an application from CRST Expedited (CRST) requesting an exemption from the requirement that a CLP holder must always be accompanied by a CDL holder with the proper CDL class and endorsements, seated in the front seat of the vehicle while the CLP holder performs BTW training on public roads or highways and requested comments. On September 23, 2016, the Agency granted CRST the exemption, effective from September 23, 2016, through September 24, 2018 (81 FR 65696). The rationale for CRST's requested exemption, and the Agency's decision to grant the exemption, was essentially the same as it was for the C.R. England exemption discussed above. On August 9, 2018, FMCSA published notice of CRST's request that FMCSA renew the initial exemption and requested public comment (83 FR 39495). On October 19, 2018, the Agency renewed CRST's exemption for a period of 5 years, effective September 23, 2018, through September 24, 2023 (83 FR 53149). On [August 7, 2023, FMCSA provisionally extended CRST's (now doing business as CRST The Transportation Solution, Inc.) exemption for an additional 5 years, through September 24, 2028, (88 FR 52241). The provisional exemption, which is subject to public comment for 30 days following publication of the exemption in the **Federal Register**, is based on CRST's assertion that it has not experienced any safety issues while operating under the exemption and will continue to monitor its safety data. The CRST exemption requests and the notices of FMCSA's disposition are available in the docket for this rulemaking.

Finally, on June 27, 2017, FMCSA granted a 5-year exemption from § 383.25(a)(1) to New Prime, Inc. (Prime) under the same terms and conditions as the exemptions issued to C.R. England and CRST, described above (82 FR 29143). In its application for exemption, Prime cited the fact that CLP holders who have passed the skills test in the State where they obtained driver training are eligible to obtain a CDL and therefore capable of safely operating a CMV. Prime stated that granting the exemption would enable CLP holders to work immediately as part of a team of drivers to transport cargo through the company's freight network before receiving their CDL credential from their State of domicile. In response to Prime's request that FMCSA extend the exemption the Agency provisionally renewed Prime's exemption for 5 years, from June 28, 2022 through June 27, 2027 (87 FR 38449), for essentially the same reasons as the provisional renewal granted to CRST in 2022. The Prime exemption requests and the notices of FMCSA's disposition are available in the docket for this rulemaking.

Waivers—§ 383.25(a)(1)

On March 28, 2020, FMCSA issued a waiver from the requirement under § 383.25(a)(1) that a CLP holder be accompanied by a CDL holder, with the proper CDL class and endorsements, seated in the front seat of the vehicle while the CLP holder operates a CMV on public roads or highways. Under the terms, conditions, and restrictions of the waiver, a CLP holder may operate a CMV on public roads or highways without an accompanying CDL holder present in the front seat of the vehicle, provided that the CDL holder is elsewhere in the cab. In addition, the CLP holder must be in possession of evidence from the testing jurisdiction, including an authorized third-party tester, that the CLP holder has passed the CDL driving skills test, and the CLP holder has a valid non-CDL driver's license, CLP, and medical certificate. The Agency granted the waiver to expedite CDL issuance to address supply chain disruptions related to the COVID–19 national emergency, including a shortage of CMV drivers. FMCSA re-issued the waiver on June 17, 2020, September 18, 2021, December 15, 2020, February 16, 2021, May 26, 2021, August 31, 2021, November 29, 2021,

[3] See ''Notice of Termination of Waiver for States Concerning Third Party CDL Skills Test Examiners in Response to the COVID–19 Emergency,'' accessible here: *https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/2022-02/Third%20Party%20Skills%20Tester%20Waiver%20-%20Notice%20of%20Termination%20-%20FINAL%20-%20Feb%203%2022.pdf;* also available in the docket of this rulemaking.

[4] 76 FR 26854, 26861 (May 9, 2011).

February 26, 2022, May 27, 2022, and August 31, 2022. The waiver expired on November 30, 2022.

C. Eligibility To Take the CDL Skills Test (§ 383.25(e))

Currently CLP holders, who have passed the required CDL knowledge test(s), are not eligible to take the CDL skills test within the 14 days following initial issuance of the CLP, a set forth in § 383.25(e). When this restriction was adopted in the May 2011 final rule, the Agency explained the mandatory waiting period was necessary to allow applicants to obtain sufficient BTW training in preparation for the skills test.

On March 24, 2020, FMCSA issued a waiver from this requirement. The terms, conditions, and restrictions of the waiver afforded States discretion to allow CLP holders to take the CDL skills test without waiting 14 days after initial issuance of the CLP, provided the CLP holder had completed applicable ELDT requirements set forth in 49 CFR part 380, subpart F. The Agency re-issued the waiver on June 17, 2020, September 18, 2021, December 15, 2020, February 16, 2021, May 26, 2021, August 31, 2021, November 29, 2021, February 26, 2022, May 27, 2022, and August 31, 2022. The waiver expired on November 30, 2022.

D. CDL Testing Requirements for Out-of-State Driver Training School Students (§ 383.79)

In the May 2011 final rule, FMCSA adopted a provision permitting a State to administer the CDL skills test in accordance with 49 CFR part 383, subparts F, G, and H, to an applicant who has taken training in that State and is to be licensed in another State (*i.e.,* the State of domicile). The testing State must electronically submit the skills test results to the State of domicile in a secure and efficient manner. The State of domicile must accept the results of a CDL skills test administered to an applicant by any other State in fulfillment of the applicant's testing requirements under § 383.71 and the State's test administration requirements under § 383.73. The Agency explained that the provision would help CLP holders obtain a CDL more efficiently by not requiring the applicant to return to their State of domicile to take the skills test after completing driver training in another State. FMCSA further noted that, since CMV driving schools routinely supply applicants with a truck or motorcoach for skills testing purposes, requiring these applicants to return to the State of domicile to take the CDL skills test would result in the applicant having to incur the cost and inconvenience of securing a CMV in which to take the test.

On March 28, 2020, FMCSA issued a waiver from the requirement that the applicant must have received training in the testing State. Under the terms and conditions of this waiver, States could elect to administer the CDL skills test to any out-of-State CLP holder, regardless of where the applicant received driver training. FMCSA noted that because the regulatory standards set forth in 49 CFR part 383, subparts F, G, H, and J set forth uniform national knowledge and skills testing procedures and antifraud measures for the States, the waiver would have no negative impact on safety. FMCSA noted that the requirement in § 383.79(a)(2) that the State of domicile must accept the results of a driving skills test administered to the applicant by any other State, in accordance with subparts F, G, and H of this part, in fulfillment of the CDL applicant's testing requirements under part 383, would continue to apply. The Agency re-issued the waiver on June 17, 2020, September 18, 2021, December 15, 2020,

February 16, 2021, May 26, 2021, August 31, 2021, November 29, 2021, February 26, 2022, May 27, 2022, and August 31, 2022. The waiver expired on November 30, 2022.

E. Transport of Empty Passenger CMVs by CDL Holders Without a P Endorsement (§ 383.93(b))

Currently the FMCSRs require that CDL holders operating passenger CMVs, including school buses, must obtain the P endorsement to transport the vehicle. In October 2017, NHDOT submitted a petition for rulemaking requesting that § 383.93 be amended to permit CDL holders who do not have a P endorsement to transport empty passenger CMVs to repair facilities. NHDOT noted that the State's rural agencies have encountered hardships based on the requirement for the driver to have a P endorsement on their CDL because, while mechanics generally have a CDL, they typically do not have a P endorsement. As a result, the State agency must either incur the expense of having the vehicle towed to the repair site or locate a driver with a P endorsement on their CDL who can drive the CMV to the repair site. NHDOT noted that the current requirement for a P endorsement does not seem necessary when there are no passengers onboard. NHDOT's petition for rulemaking is available in the docket for this rulemaking.

In 2019, the Agency received multiple requests for exemption from the requirement that a CDL holder transporting an empty bus be required to have a P endorsement. On August 13, 2019, the Agency responded to those requests by posting an enforcement notice on FMCSA's website announcing that the Agency does not intend to take enforcement action against CDL holders driving an empty bus from the manufacturer to the local distributor or in a driveaway-towaway operation without the P and S endorsements, provided the driver possesses a bill of lading showing the trip is for delivery only. The enforcement notice is available at *https://www.fmcsa.dot.gov/mission/chief-counsel/enforcement-notice.*

In March 2022, FMCSA granted NHDOT's petition for rulemaking to amend § 383.93 to permit CDL holders to operate a passenger CMV without having a P endorsement on their CDL when the driver is transporting the vehicle to a repair facility and the vehicle has no passengers onboard. The proposed amendment to § 389.93(b) is based, in part, on NHDOT's petition.

VI. Discussion of Proposed Rulemaking

The Agency proposes to improve the efficiency and convenience of obtaining a CDL by increasing flexibilities in certain CDL licensing processes, without negatively impacting safety. Additionally, the NPRM would strengthen the program integrity of CDL knowledge tests administered by third-party examiners and provide flexibility for CDL holders transporting empty passenger CMVs. As discussed above, the proposed revisions stem from the temporary regulatory relief FMCSA provided in response to the impact of the COVID–19 public health emergency on SDLAs' operations and on the supply chain and from petitions for rulemaking submitted by ATA and NHDOT.

A. Definitions

The NPRM would add two new definitions to § 383.5: (1) *third-party knowledge examiner,* defined as ''a person employed by a third-party knowledge tester who is authorized by the State to administer the CDL knowledge tests specified in subparts G and H of this part;'' and (2) *third-party knowledge tester,* defined as ''a person (including, but not limited to, another State, a motor carrier, a private driver training facility or other private institution, or a department, agency or instrumentality of a local government) authorized by the State to employ knowledge test examiners to administer the CDL knowledge tests specified in subparts G and H of this part.'' The addition of these terms is necessary to accommodate the proposed revisions

pertaining to third-party knowledge testing, as described below.

FMCSA also proposes to revise the current term *third-party tester* to read *third-party skills tester* in light of the added definition for *third-party knowledge test examiner.*

B. CLP Holders Who Have Passed the Skills Test

Currently, a CLP is considered a valid CDL to operate a CMV on public roads or highways only for the purpose of BTW training, subject to certain conditions. One of those conditions, set forth in § 383.25(a)(1), states that the CLP holder must at all times be accompanied by the holder of a valid CDL who has the proper CDL group and endorsement(s) necessary to operate the CMV. The CDL holder must at all times be physically present in the front seat of the vehicle next to the CLP holder or, in the case of a passenger CMV, directly behind or in the first row behind the driver and must have the CLP holder under observation and direct supervision. When adopting this requirement in the May 2011 final rule, FMCSA noted that it would not be safe to permit an inexperienced driver who has not passed the skills test to operate a CMV unaccompanied.[5]

The Agency proposes to amend § 383.25(a)(1) by adding an exception permitting a CLP holder who has passed the skills test to operate a CMV for purposes other than BTW training without having a CDL holder sitting in the front passenger seat or to operate an empty passenger CMV, including a school bus, or an empty tank vehicle,[6] without a CDL holder seated directly behind, or in the first row behind, the CLP holder. The proposed exception would apply only if the CLP holder has already passed the skills test, possesses documentary evidence from the testing State of having passed the skills test, and the holder of a valid CDL is physically present in the CMV. The Agency believes the proposed revision would not negatively affect safety, because, by passing the skills test, the CLP holder has demonstrated their ability to safely operate the CMV.

While the Agency anticipates this flexibility would be used primarily by CLP holders who pass the skills test in a State other than their State of domicile, the exception also applies when a CLP holder passes the skills test in their State of domicile. For example, if a CLP holder passes the skills test administered by a third-party skills test examiner at a testing site located miles from the nearest SDLA, the CLP holder could operate a CMV under this exception. The Agency notes that CLP holders who pass the skills test in their State of domicile and receive a temporary CDL authorizing them to operate a CMV until they receive the CDL credential in the mail would not need to use the exception because they would no longer be CLP holders.

The NPRM would provide flexibility for CLP holders, who, for example, obtain driver training outside their State of domicile by allowing them to be productively employed as a CMV driver before formally receiving the CDL document issued by their State of domicile. As noted above in the discussion of the previously granted exemptions from § 383.25(a)(1), CLP holders operating under the exception could function as part of a team of drivers to transport cargo until they receive the CDL credential from their State of domicile. The proposed exception may therefore ease supply chain disruptions related to CMV driver shortages while retaining an adequate assurance of safety provided by the conditions under which these operations are allowed.

C. Eligibility To Take the CDL Skills Test

Currently, applicants who obtain a CLP after passing the required knowledge test(s) are not eligible to take the CDL skills test during the 14 days following initial issuance of the CLP, as set forth in § 383.25(e). The purpose of this mandatory waiting period is to allow time for applicants to obtain CMV driver training in preparation for taking the skills test. On February 7, 2022, FMCSA implemented ELDT standards, including required BTW training on a driving range and on public roads, set forth in 49 CFR part 380, appendices A through D. States must verify that CLP holders completed the required ELDT before administering the skills test, as set forth in § 383.73(b)(11). The Agency therefore proposes to remove paragraph (e) because the 14-day waiting period is no longer necessary. The elimination of the mandatory waiting period would permit applicants who successfully complete the performance-based BTW training less than 14 days after initial issuance of the CLP to obtain a CDL sooner than they can today. The Agency notes that the ELDT regulations do not prohibit applicants from scheduling the skills test before they have completed ELDT, which further increases the efficiency of the skills testing process.

D. CDL Skills Testing for Out-of-State Applicants

Section 383.79(a)(1) permits, but does not require, an SDLA to allow an out-of-State CDL applicant to take the CDL driving skills test if the applicant also received training in that State. The skills test must be administered in accordance with 49 CFR part 383, subparts F, G, and H and test results must be transmitted electronically directly from the testing State to the licensing State (*i.e.,* State of domicile) in a direct, efficient, and secure manner. The NPRM proposes to remove the restriction that the out-of-State applicant must have obtained training in the testing State to take the CDL skills test in the testing State. SDLAs thus would be permitted to administer the CDL driving skills test to out-of-State CDL applicants regardless of where the applicant received driver training. The requirement that the State of domicile accept the skills test results in fulfillment of the applicant's testing requirements under § 383.71, and the State's testing administration requirements under § 383.73, as currently set forth in § 383.79(a)(2), would remain unchanged.[7]

FMCSA proposes this revision so that CDL applicants can complete the required skills testing as soon as possible without compromising highway safety. Under the proposal, CLP applicants would be free to schedule their skills test according to their needs or convenience. As noted above, the testing State may, for example, be where an applicant obtained training and has access to a CMV in which to take the skills test, or it may be a neighboring State with a shorter wait list for securing a skills test appointment than the applicant's State of domicile. In any event, the requirement that training must occur in the testing State is no longer necessary with implementation of FMCSA's uniform minimum ELDT requirements on February 7, 2022. Applicants must now comply with the Federal ELDT standards, set forth in 49 CFR part 380, subpart F, before taking the skills test, thereby ensuring qualified applicants.

[5] *Ibid.*

[6] Under § 383.25(a)(5)(i) and (ii) respectively, CLP holders are prohibited from operating a CMV carrying passengers or a school bus carrying passengers. For purposes of the prohibition, Federal/State auditors and inspectors, test examiners, other trainees, and the CDL holder accompanying the CLP holder as prescribed by paragraph (a)(1), are not considered passengers. Under § 383.25(a)(5)(iii) a CLP holder may only operate an empty tank vehicle and is prohibited from operating any tank vehicle that previously contained hazardous materials that has not been purged of any residue.

[7] 49 CFR 383.79(b) currently addresses CDL application requirements for active duty military service members. The NPRM does not propose to amend those provisions.

Under the proposal, the testing State must continue to administer the skills test in accordance with existing requirements in 49 CFR part 383, subparts F, G, and H, which would ensure consistency in skills test execution.

The Agency requests comment from SDLAs concerning the operational impact of this proposed revision on either the testing State or the State of domicile.

E. Third-Party Knowledge Examiners and Testers

As explained above in Section V., in accordance with FMCSA's regulatory guidance issued on February 3, 2022, a State's discretionary use of third-party knowledge examiners is not prohibited by statute or regulation. States may therefore permit third-party knowledge examiners to administer the knowledge test for CDL classes and endorsements. Currently there are no regulatory requirements governing a State's use of third-party knowledge examiners. The February 2022 guidance represented a change in the Agency's position on States' use of third-party knowledge examiners, rescinding previous guidance, initially issued in 1993 by the Federal Highway Administration,[8] FMCSA's predecessor agency, stating that States should not permit third-party knowledge testing outside the presence of a State knowledge examiner. In explaining that change, FMCSA noted that it planned to undertake a rulemaking to establish standards for States opting to permit the CDL knowledge test to be administered by third-party examiners.

In the interim, FMCSA provided guidance to the States recommending, but not requiring, best practices for States allowing third-party knowledge testing, including following the training, certification, and record check requirements currently applicable to State knowledge examiners and the auditing and monitoring requirements currently applicable to third-party skills examiners and testers. Both the February 2022 notice of regulatory guidance and FMCSA's subsequent ''best practices'' guidance are available in the docket for this rulemaking.

Consistent with the current regulatory guidance, the NPRM proposes that States permitting third-party examiners to administer CDL knowledge tests be subject to the same training (including refresher training), testing, certification, and criminal background check requirements applicable to State knowledge examiners, as set forth in § 384.228, and the auditing and monitoring requirements applicable to third-party skills examiners, as set forth in § 384.229. Because certain provision of § 384.228 already apply to third-party skills examiners, FMCSA proposes to except certified third-party skills test examiners who also administer the knowledge tests from those provisions to avoid the application of duplicative requirements. Additionally, FMCSA proposes to establish the conditions under which States would be authorized to permit third-party knowledge testing, which currently apply only to third-party skills testing, as set forth in § 383.75. The NPRM would add a new requirement that third-party knowledge testing be administered electronically and securely to minimize the opportunity for negligence or fraud that may exist when knowledge tests are administered on paper.

The Agency believes application of these standards to third-party knowledge examiners and testers would further ensure the integrity of the knowledge testing program, just as the requirements in § 384.228 ensure that State knowledge examiners are adequately trained and otherwise qualified, and as §§ 384.229 and 383.75 currently ensure the integrity of third-party skills testing.

FMCSA invites comment on the proposed applicability of these standards to third-party knowledge examiners and testers.

F. P Endorsement Requirements

In accordance with § 383.93(b)(2) and (5), CDL holders transporting CMVs designed to carry passengers, including school buses, must have a P endorsement. Pursuant to § 393.93(c)(2), drivers must pass a specialized knowledge test and pass the skills test to obtain the P endorsement. Under § 383.117, the P endorsement knowledge test topics include loading/unloading passengers, dealing with unruly passengers, procedures for an emergency evacuation of the vehicle, and other operating practices and procedures. The applicant must take the P endorsement skills test in a passenger vehicle satisfying the requirements of the vehicle group (*e.g.,* Group B). The P endorsement is intended primarily to ensure the driver has the necessary skills and knowledge to safely transport passengers and does not otherwise require additional on-road driving skills beyond those already required to hold a CDL of the appropriate class. As discussed above, the Agency's current enforcement policy permits a CDL holder to transport a passenger CMV without having the P endorsement on their CDL when the vehicle is being delivered to a distributor from the manufacturer, or in a driveaway-towaway operation, when there are no passengers in the vehicle except the driver and the driver possesses a bill of lading or other documentation indicating the trip is for delivery only. FMCSA proposes to amend § 383.93(b) to create an exception to the requirement that CDL holders have a P endorsement to operate an empty passenger CMV, including an empty school bus, when the vehicle is being transported for delivery or in a *driveaway-towaway operation,* as defined in § 390.5T. FMCSA notes that an S endorsement is not required to operate an empty school bus because the S endorsement is required only when the bus is transporting pre-primary, primary, or secondary school students from home to school, school to home, or to and from school-sponsored events, as set forth in the definition of *school bus* in § 383.5.

The Agency proposes this change to provide enhanced flexibility in the delivery of empty passenger CMVs to a distributor or a repair facility without compromising passenger safety. FMCSA emphasizes that the underlying CDL requirements are unaffected by the proposed change; the driver must possess a CDL of the appropriate class for operating the passenger CMV, such as a Class B CDL to operate a motorcoach. As NHDOT noted in its petition for rulemaking, while mechanics generally have a valid CDL, most do not have the P endorsement. The proposed change would facilitate the limited transportation of passenger CMVs, thereby ensuring the timely delivery of the vehicle from the manufacturer or the delivery of the vehicle to effect necessary repairs. In addition, the proposed amendment would allow for timely removal of a damaged (but still drivable) vehicle from the roadside following a crash. The Agency concludes that delivery documentation referenced in the current guidance, such as a bill of lading, need not be a regulatory requirement. As explained above, in FMCSA's judgment, an empty passenger CMV can be transported by a driver holding only a CDL of the appropriate class with no impact on passenger safety. Delivery documentation requirements would therefore impose administrative burden on the transportation of empty CMVs without improving safety.

The Agency requests comment on the proposed amendment.

[8] See, 58 FR 60734, 60739 (Nov. 17, 1993).

G. Major Issues on Which the Agency Seeks Comment

While the Agency invites comment on all aspects of the NPRM, we are particularly interested in receiving comments that address the following issues:

1. What forms of documentation would be acceptable to demonstrate to a law enforcement officer or CMV inspector that the CLP holder operating the CMV has successfully completed the CDL skills test? What form of documentation did States acting under the authority of the waiver or exemptions provide for CLP holders who passed the skills test in their State?

2. Should a CLP holder be permitted to operate a CMV under the proposed exception to § 383.25(a)(1) until the CLP expires or should there be a shorter time period after passing the skills test that the CLP holder must obtain the CDL credential? Please explain your answer.

3. Did SDLAs relying on the waiver allowing a CLP holder to take the CDL skills test without waiting 14 days following issuance of the CLP experience a change in the applicant passing rate for the road test portion of the skills test? Were there a large number of applicants who took the skills test in your State without waiting 14 days? Did these SDLAs see a reduction in skills testing backlogs in their State?

4. Are there safety or operational concerns associated with lifting the mandatory 14-day waiting period between obtaining a CLP and taking the CDL skills test? Would your State impose a waiting period between CLP issuance and the CLP holder taking the skills test, even if it was no longer be required? Please explain your answer.

5. The NPRM proposes to permit a State to administer the CDL skills test to an out-of-State CLP holder who has not obtained training in the testing State. If adopted, would removing this restriction have any impact on your State's decision to permit out-of-State CLP holders to take the skills test in the State? Please explain your answer.

6. With a few noted exceptions, the NPRM proposes to apply training and oversight standards currently applicable to third-party skills testers to third-party knowledge testers. Do you believe any of these existing requirements are not relevant to third-party knowledge testers? If so, please explain your answer.

7. Should State knowledge examiners be included in the auditing and monitoring requirements proposed for third-party knowledge examiners in new § 384.229(b)(2) and (3) to minimize fraud? Why or why not?

8. What form of oversight do States currently provide for State knowledge examiners? If State knowledge examiners were included within the scope of the oversight requirements proposed in new § 384.229(b)(2) and (3), would that result in additional costs for the States? If so, please explain and estimate the additional costs.

9. Do you agree or disagree with the proposed requirement that CDL knowledge tests administered by third-party examiners be securely conducted electronically to minimize fraud? Please explain your answer.

10. FMCSA is aware that several States currently permit third-party knowledge testing and that some States permitted third party knowledge testing in accordance with waivers in effect between July 1, 2020, and February 3, 2022. For these States, do/did you permit third-party examiners to administer the tests in a physical location outside of the SDLA (*e.g.,* a testing center)? If not, why not? If so, please describe the specific measures you take/took to ensure the integrity of the third-party knowledge testing process in a separate physical location. For example, how did/does your State verify the applicant's identity before they take the knowledge test and that applicants take the test themselves without assistance, such as reference materials?

11. Would your State consider allowing third-party knowledge testing in accordance with the new requirements proposed by the NPRM? Why or why not? What factors do you believe will influence your decision?

12. The NPRM estimates that the proposed application of training, record check, and oversight requirements to States opting to utilize third-party knowledge examiners and testers would result in additional costs to those States and has preliminarily identified cost estimates in this NPRM. Do you agree with these estimated costs? Why or why not? Do these costs change if the State already has an auditing and monitoring program for third-party skills examiners?

13. How long would States need to adapt their administrative processes and procedures to accommodate the proposed changes? Would any of the proposed changes require a modification of SDLAs' IT systems or a change in underlying State law?

14. Does the proposal to except CDL holders transporting empty passenger CMVs, including school buses, from having a P endorsement in driveway-towaway operations, or when transporting the vehicle from the manufacturer to a distributor, raise any safety concerns? Why or why not?

VII. Section-by-Section Analysis

This section summarizes the changes proposed for 49 CFR parts 383 and 384 in numerical order.

A. Proposed Changes to Part 383

Part 383 establishes standards for the issuance and administration of CLPs and CDLs. The Agency proposes to amend Part 383 in the following ways:

Section 383.5 Definitions

FMCSA proposes to add definitions of the terms *third-party knowledge examiner* (a person employed by a *third-party knowledge tester* who is authorized by the State to administer the CDL knowledge tests specified in subparts G and H of this part) and *third-party knowledge tester* (a person (including, but not limited to, another State, a motor carrier, a private driver training facility or other private institution, or a department, agency, or instrumentality of a local government) authorized by the State to employ third-party knowledge examiners to administer the CDL knowledge tests specified in subpart G and H of this part). Additionally, FMCSA would revise the current term *third party tester* to read *third-party skills tester* and add a hyphen to the term ''third party'' in the definition of *third party skills test examiner.*

Section 383.25 Commercial Learner's Permit (CLP)

FMCSA proposes to revise § 383.25 by adding an exception to paragraph (a)(1) that would permit CLP holders who have passed the relevant CDL skills test(s) and possess documentary evidence of having done so, to operate a CMV on public roads or highways for purposes other than BTW training, as long as a CDL holder with the proper CDL class and endorsements to operate the CMV is physically present in the vehicle.

The Agency also proposes to amend § 383.25 by removing paragraph (e), which states that CLP holders are not eligible to take the CDL skills test in the 14 days following initial issuance of the CLP.

Section 383.75 Third Party Testing

The NPRM proposes to amend § 383.75 by consolidating existing paragraphs (a) through (c) into new paragraph (a) and adding a new paragraph (b). Proposed new paragraph (a) would contain the current auditing and monitoring requirements applicable to third party skills testers as set forth

in current paragraphs (b) and (c). New paragraph (b) would contain auditing and monitoring requirements for States choosing to authorize third party knowledge testers and examiners. Section 383.75 currently imposes auditing and monitoring requirements only on States that rely on third party skills testers and examiners. The proposed oversight requirements in new paragraph (b) governing a State's use of third party knowledge testers would be based on the relevant provisions now applicable to third party skills testers. FMCSA also proposes to add a requirement that all knowledge tests administered by third party examiners be conducted electronically. The NPRM also proposes that the title of § 383.75 be changed from ''Third party testing'' to ''Third party skills and knowledge testing'' to reflect the proposed addition of new paragraph (b).

Section 383.79 Driving Skills Testing of Out-of-State Students; Knowledge and Driving Skills Testing of Military Personnel

FMCSA proposes to revise § 383.79(a)(1), by removing the restriction requiring an applicant taking the CDL skills test in a State other than the licensing State (*i.e.,* the applicant's State of domicile) to have obtained training in the testing State. Under the proposed revision, CDL applicants would be able to take the skills test in any State, regardless of where they obtained driver training.

Section 383.93 Endorsements

The NPRM proposes to amend § 383.93(b), which requires drivers to obtain State-issued endorsements to their CDL when operating specified type of CMVs, including passenger CMVs (§ 383.93(b)(2)) and school buses (§ 383.93(b)(5)). The amendment would create an exception from the requirement that a driver obtain a P endorsement when operating passenger CMVs, including school buses, when the vehicle is empty of all passengers other than the driver and is being transported from the manufacturer to a distributor, or in a *driveway-towaway operation,* as defined in § 390.5T.

B. Proposed Changes to Part 384

Part 384 establishes standards and procedures to ensure that the States comply with 49 U.S.C. 31311(a), which sets forth the requirements for States' participation in the CDL program and specifies the consequences of State noncompliance. The Agency proposes to amend part 384 in the following ways:

Section 384.228 Examiner Training and Record Checks

This section requires States to follow certain examiner training and record check protocols for State knowledge and skills examiners and third-party skills examiners. The Agency proposes to include third party knowledge examiners within the scope of the training and record check requirements now applicable to State knowledge examiners, as set forth in § 384.228(a) through (c) (training standards and content, completion of formal training course, passing the course exam, and the State's certification of the examiner); (f)(1) (completion of refresher training every four years); (f)(3) and (4) (refresher training course content); (h) (nationwide criminal background checks); (i) (State's retention of records related to examiner background checks training, and certification; (j) State's recission of examiner certification for any examiner failing to complete mandatory refresher training; and (k) (required examiner training content may be supplemented by State-specific material related to administering CDL knowledge and skills tests). Most of these requirements currently apply to State and third-party skills test examiners as well as State knowledge examiners. The Agency does not intend to impose duplicative training and record check requirements on certified skills test examiners who also administer knowledge tests. Accordingly, to the extent that certified skills test examiners are already subject to the provisions of § 384.228 listed above, States would be excepted from the training and record check requirements regarding third-party knowledge examiners.

Additionally, FMCSA proposes to remove paragraph (g), which requires States to conduct criminal background checks of all skills test examiners prior to certifying them to administer skills tests. This provision, originally adopted in the May 2011 final rule, is no longer necessary in light of current paragraph (h), subsequently amended in 2013 to require, in paragraph (h)(1), that criminal background checks be completed for all State and third-party test examiners before hiring and, in paragraph (h)(2), to require that criminal background checks be completed for any current State or third-party test examiner who has not had a criminal background check. FMCSA would also revise current paragraph (h)(1) by adding an exception from its requirements for current third-party skills testers who have maintained their CDL test examiner certification and have already been subject to a nationwide criminal background check. The remaining paragraphs would be renumbered accordingly.

Section 384.229 Skills Examiner Auditing and Monitoring

FMCSA proposes to amend § 384.229, which requires States to conduct auditing and monitoring of State and third-party skills examiners. The proposal would divide this section into two paragraphs, one setting forth the requirements currently applicable to third-party skills test examiners, which would remain unchanged, and the other setting forth proposed auditing and monitoring requirements applicable to third-party knowledge examiners.

VIII. Severability

As discussed above in Section III. Legal Basis, FMCSA is authorized by 49 U.S.C. chapter 313 to promulgate regulations governing the issuance of CDLs. The NPRM is also based on several concurrent authorities to establish minimum standards for the fitness of drivers operating CMVs and to promulgate standards for the safe operation of CMVs.

Consistent with these statutory authorities, the NPRM proposes revisions to 49 CFR part 383, Commercial Licensing Standards; Requirements and Penalties and 49 CFR part 384, State Compliance with Commercial Driver's License Program. The primary purpose of the NPRM is to enhance the flexibility and efficiency of the CDL program by proposing the removal of several current regulatory restrictions without compromising safety. The NPRM would improve safety by proposing measures to establish qualification requirements for third-party knowledge examiners and monitoring and oversight requirements for States choosing to utilize third-party knowledge testing.

The revisions proposed in the NPRM primarily pertain to discrete regulatory requirements proposed in 49 CFR parts 383 and 384. Therefore, FMCSA finds that the various provisions of the NPRM pertaining to 49 CFR part 383 and the proposed change to part 384 are severable and able to operate functionally if severed from each other in a final rule resulting from this NPRM. In the event a court were to invalidate one or more of the unique provisions of a final rule, the remaining provisions should stand, thus allowing FMCSA to continue to fulfill its Congressionally authorized role of regulating the issuance of CDLs and promoting the safe operation of CMVs.

IX. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), E.O. 14094 (Modernizing Regulatory Review), and DOT Regulatory Policies and Procedures

The Office of Information and Regulatory Affairs (OIRA) determined that this proposed rule is not a significant regulatory action under section 3(f) of E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and by E.O. 14094 (88 FR 21879, Apr. 11, 2023), Modernizing Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. This rule is also not significant within the meaning of DOT regulations (49 CFR 5.13(a)). Accordingly, OMB has not reviewed it under these Orders.

This proposal would (1) remove the restriction allowing a State to administer the CDL skills test to a CLP holder who is domiciled in another State only if the applicant obtained training in the testing State; (2) permit a CLP holder who has passed the CDL skills test to operate a CMV on public roads for purposes other than BTW training, provided the CLP holder has evidence of passing the CDL skills test and a qualified CDL holder is physically present in the CMV; (3) eliminate the requirement that an applicant wait at least 14 days to take the CDL skills test following initial issuance of the CLP; (4) establish qualification requirements for third-party CDL knowledge examiners and auditing and monitoring requirements for States that authorize third-party knowledge testing; and (5) remove the requirement that a CDL holder have a P endorsement when a passenger CMV is being transported from the manufacturer to a distributor, or in a driveaway-towaway operation, and the vehicle is not carrying any passengers. As discussed below, FMCSA believes these changes would improve the efficiency and convenience of CDL issuance, provide needed flexibility for CLP holders who have demonstrated their ability to safely operate a CMV by passing the CDL skills test, and improve highway safety by ensuring the integrity of third-party CDL knowledge testing. The proposed rule could affect States, third-party knowledge examiners, CDL applicants, P endorsement applicants, and motor carriers.

States

States that currently choose to allow third-party knowledge testing in their jurisdiction could be impacted by this rule to the extent that the proposed requirements differ from current State practices. In accordance with regulatory guidance adopted on February 3, 2022, States may authorize the use of third-party knowledge examiners as long as they adhere to the CDL knowledge test standards and requirements set forth in 49 CFR part 383, subparts G and H. FMCSA does not presently impose other regulatory requirements on States' use of third-party knowledge testing; the NPRM would establish such standards. FMCSA is aware that following publication of the February 3 guidance, at least one State passed legislation authorizing third-party skills testers to administer the CDL knowledge tests in that State. The Agency does not know whether other States currently permit third-party knowledge testing and requests comment from States that may currently allow this practice. Under the proposal, the decision by an SDLA to permit third-party examiners to provide knowledge tests would be discretionary, and FMCSA is therefore unable to predict how many SDLAs would permit third-party examiners to administer the CDL knowledge tests. FMCSA cannot predict the number of States that would permit third-party testing as proposed in the NPRM, but requests comment on the number of States that would do so.

Third-Party Examiners

Based on a survey conducted by American Association of Motor Vehicles Administrators (AAMVA) to which 38 States responded,[9] FMCSA estimates that there are over 3,000 third-party skills test examiners. FMCSA assumes that some of these existing third-party skills examiners would also become third-party knowledge examiners, but does not have a basis to estimate the number of third-party knowledge examiners resulting from this rule.

CDL Knowledge Test Applicants

A CDL applicant must hold a CLP in order to take the CDL skills test. FMCSA estimates that approximately 600,000 to 700,000 CLPs are issued annually nationwide. This estimate is based primarily on information from the Commercial Driver's License Information System (CDLIS), a nationwide computer system, administered by the American Association of Motor Vehicle Administrators, that enables SDLAs to ensure that each commercial driver has only one driver's license and one complete driver record. A master pointer record is typically added to CDLIS within 10 days of issuing a CLP to a driver who is believed to have never held one previously, and is therefore a reasonable proxy for estimating the number of CDL knowledge test applicants. However, FMCSA does not anticipate that all of these CDL knowledge test applicants would be impacted by this rule.

FMCSA notes that, because the Agency cannot estimate the number of States that would choose to permit third-party knowledge examiners in accordance with the proposed rule, the extent to which this population would be affected by the proposed rule is unknown.

Motor Carriers

The proposal would permit a CLP holder who has passed the CDL skills test but has not yet been issued the CDL credential to operate a CMV for purposes other than BTW training without being accompanied by a CDL holder in the front passenger seat or, in the case of a passenger-carrying CMV, directly behind or in the first row behind the driver, as long as a CDL holder is present in the vehicle. Motor carriers may be affected by this proposal, if they currently employ CLP drivers that have passed the skills test but have not yet obtained the CDL credential from their State of domicile. Other than the number of impacted drivers estimated in the exemption applications submitted by CRST, CR England, and Prime, FMCSA is unable to predict the overall population of drivers that could be impacted by this provision. Additionally, FMCSA does not know how many CLP holders have passed their skills test but have not yet received their CDL credential, or how many trips would be affected by this proposed change.

Costs, Benefits and Transfer Payments

Costs

This proposal would remove current regulatory restrictions related to CDLs and CLPs and impose standards for third-party knowledge examiners and monitoring and auditing requirements applicable to States choosing to allow third-party knowledge testing. It could result in costs to third-party examiners and States, and may result in savings to motor carriers and drivers.

[9] Information collected by U.S. Department of Transportation (DOT), Federal Motor Carrier Safety Administration (FMCSA) in March 2021 from the American Association of Motor Vehicles Administrators (AAMVA).

Under the proposal, third-party knowledge examiners would be required to take a 20-hour training course every 3 years in order to administer knowledge tests. There is not a specific skill set required to be a knowledge test examiner, and many different occupations could proctor knowledge test exams. For illustrative purposes, FMCSA estimates that training and development managers (BLS 11–3131) with a fully loaded wage rate of $99 ($99 = $57.69 + ($57.69 × 0.505 fringe benefit rate) + ($57.69 × 0.21 overhead rate) would undergo the 20-hour training course and become third-party knowledge test examiners.[10] FMCSA assumes that this training is provided online and would not require travel expenses. Therefore, the cost for each examiner would be $1,980 ($99 × 20). FMCSA estimates that ⅓ of the 14,000 examiners, or 4,667, would take the training each year, at a cost of approximately $9.2 million per year, or $92.4 million over the 10-year analysis period. FMCSA estimates that the 10-year cost of this provision would total $81 million discounted at 3 percent, and $69 million discounted at 7 percent. Annualized costs would total $9.24 million discounted at 3 percent and $9.24 million discounted at 7 percent (all in 2021 dollars). FMCSA proposes to further require that the State certify that each third-party knowledge examiner has completed a formal CDL knowledge test examiner training course.

FMCSA is proposing that knowledge tests be administered electronically but is not proposing requirements on the physical location of the knowledge testing site. For instance, FMCSA could require that knowledge tests are taken in person at a designated physical location other than the SDLA or allow third-party knowledge test administrators to proctor exams without a State employee being present. FMCSA requests comments on these alternatives, and whether remote physical testing site requirements should be adopted.

States that opt to allow third-party knowledge testing would be required to develop an auditing and monitoring program to ensure the integrity of the knowledge testing program. FMCSA assumes that States with existing third-party skills testing programs already have auditing programs in place. FMCSA requests comment on the additional burden of creating a third-party knowledge testing auditing process for these States. FMCSA also requests comment on whether States that do not have third-party skills testing programs would initiate a third-party knowledge testing program, and on the cost to set up and administer an auditing program. Further, at least one State has indicated that the proposed changes could reduce demands on SDLA service centers, resulting in a cost savings, by a reduction in State-administered knowledge exams. FMCSA requests comment on this issue. FMCSA invites comment on whether the Agency should include State knowledge examiners in the auditing and monitoring requirements proposed for third-party knowledge examiners, which would be a new requirement imposed on States. FMCSA seeks comment on costs associated with any existing auditing and monitoring programs that States may have for knowledge test examiners, and on the additional costs that would result should FMCSA impose such requirements.

The proposal would result in cost savings for motor carriers and drivers because, after the CLP holder passes the skills test, the CDL holder would be allowed to rest in the sleeper berth, thereby saving on-duty time under the HOS rules that would otherwise be lost riding in the passenger seat, overseeing the CLP holder. The proposed change would therefore allow the CLP holder, with proof of a passing CDL skills test, to operate the vehicle in a wage-earning capacity. FMCSA does not know how many CLP drivers pass their skills test but do not immediately receive their CDL credential, nor does FMCSA know the number of vehicle miles or trips that might be impacted by this rule. As such, FMCSA cannot estimate the cost savings that could result from this provision but requests comment on the impact of this proposed change.

Lastly, this proposed rule clarifies that CDL holders who have not obtained the P endorsement may operate an empty passenger CMV, including a school bus, from the manufacturer to the distributor or in a driveaway-towaway operation. This proposed change, which is consistent with FMCSA's current enforcement policy, reflects the fact that the P endorsement is intended primarily to ensure the driver has the necessary skills and knowledge to safely transport and evacuate passengers. The proposed regulatory change would clarify that the driver is not required to have a P endorsement when transporting an empty passenger CMV, which could allow for an increase in cost savings without impacting passenger safety. Motor carriers would no longer need to incur the expense of having the vehicle towed to the repair site or locating a driver with a P endorsement on their CDL who can drive the CMV to the repair site. The proposed amendment would ensure consistency of enforcement and broaden stakeholder awareness of this flexibility.

Benefits

As discussed above, FMCSA believes that the proposal would improve highway safety by enhancing the integrity of third-party CDL knowledge testing. The proposal would also create positive change for drivers, industry stakeholders, and SDLAs by expanding knowledge and skills test accessibility, permitting CDL holders to operate empty passenger CMVs in limited circumstances without obtaining the P endorsement, and eliminating the 14-day waiting period between receiving a CLP and taking the CDL skills test.

Third-party knowledge testing would provide additional flexibility for CLP applicants, who may be able to obtain their CLP sooner from a third-party examiner than by taking the tests at the SDLA. The knowledge tests administered by third-party examiners would be subject to the same testing standards and methods used by State knowledge examiners, as set forth in 49 CFR part 383 subparts G and H. The NPRM proposes that knowledge tests given by third parties be administered electronically, minimizing opportunity for fraud.

The proposal would expand the States' discretion to provide skills testing to out-of-State applicants, regardless of the State in which training was obtained. This provision would expand skills test accessibility, allowing applicants to obtain a CDL sooner by scheduling the skills test in a State with shorter waiting times. All States must conduct skills testing, in accordance with the uniform minimum requirements set forth in 49 CFR part 383, subparts G and H. Thus, the State in which skills testing occurs does not impact how the driver's skills are evaluated during the test.

The P endorsement is intended to ensure that the driver has the knowledge and skills necessary to safely transport passengers and to evacuate the CMV in case of emergency. The proposed change would therefore enhance flexibility in the transport of empty passenger CMVs to distributors, dealers, purchasers, and repair facilities without compromising passenger safety.

Lastly, the elimination of the mandatory 14-day waiting period between initial issuance of the CLP and taking the CDL skills test would permit

[10] U.S. Department of Labor (DOL), Bureau of Labor Statistics (BLS). *Occupational Employment and Wage Statistics (OEWS). National. May 2022.* Available at: *https://www.bls.gov/oes/current/oes_nat.htm* (accessed September 8th, 2023).

applicants who successfully complete the performance-based BTW range and road training in less than 14 days to obtain a CDL and be productively employed sooner than they can today. Following the implementation of the ELDT regulations in February 2022, this waiting period is no longer necessary. The Agency has not identified any other positive or negative benefits to society that would result from this proposed change to § 383.25(e).

Transfer Payments

There are also certain transfer payment effects that may occur as a result of this proposed rule. Transfer payments are monetary payments from one group to another that do not affect total resources available to society, and therefore do not represent actual costs or benefits of the rule. SDLAs currently incur costs and receive fees to administer knowledge tests to CLP applicants. If a State chooses to allow third-party examiners to administer the knowledge test to CLP applicants, CLP applicants would no longer be required to take the knowledge test at the SDLA, streamlining the process to begin CDL driver training. In this instance, the cost of providing the knowledge test and the associated revenue for the provision of that service would be transferred to the third-party tester. The Agency is unable to predict the amount of these transfer payments as they would occur only in those States allowing third-party examiners to administer the knowledge test.

B. Congressional Review Act

This rule is not a *major rule* as defined under the Congressional Review Act (5 U.S.C. 801–808).[11]

C. Advance Notice of Proposed Rulemaking

Under 49 U.S.C. 31136(g), FMCSA is required to publish an advance notice of proposed rulemaking (ANPRM) or proceed with a negotiated rulemaking, if a proposed rule is likely to lead to the promulgation of a major rule. As this proposed rule is not likely to result in the promulgation of a major rule, the Agency is not required to issue an ANPRM or to proceed with a negotiated rulemaking.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996,[12] requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term *small entities* comprises small businesses and 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 (5 U.S.C. 601(6)). Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities, and mandates that agencies strive to lessen any adverse effects on these businesses.

Affected Small Entities

This rule has the potential to impact States, third-party knowledge examiners, CDL skills test applicants, and motor carriers. Under the standards of the RFA, as amended, States are not small entities because they do not meet the definition of a *small entity* in section 601 of the RFA. Specifically, States are not small governmental jurisdictions under section 601(5) of the RFA, both because State government is not among the various levels of government listed in section 601(5), and because, even if this were the case, no State, including the District of Columbia, has a population of less than 50,000, which is the criterion to be a small governmental jurisdiction under section 601(5) of the RFA.

CDL applicants are not considered small entities because they do not meet the definition of a *small entity* in Section 601 of the RFA. Specifically, drivers are considered neither a small business under Section 601(3) of the RFA nor a small organization under Section 601(4).

Under the RFA, as amended, motor carriers and third-party knowledge testers may be considered small entities based on the SBA-defined size standards used to classify entities as small. SBA establishes separate standards for each industry, as defined by the North American Industry Classification System (NAICS). This rule could affect motor carriers in many different industry sectors in addition to the Transportation and Warehousing sector (NAICS sectors 48 and 49); for example, the Construction sector (NAICS sector 23), the Manufacturing sector (NAICS sectors 31, 32, and 33), and the Retail Trade sector (NAICS sectors 44 and 45). FMCSA anticipates that third-party knowledge testers would largely be employed by testing entities that currently employ third-party skills examiners. Many third-party skills examiners are also training providers at universities, technical and trade schools, and other training focused institutions that operate within the Educational Services sector (NAICS sector 61). Industry groups within these sectors have size standards for qualifying as small based on the number of employees (*e.g.,* 500 employees), or on the amount of annual revenue (*e.g.,* $27.5 million in revenue). Not all entities within these industry sectors will be impacted by this rule, and therefore FMCSA cannot determine the number of small entities based on the SBA size standards.

Impact

CDL knowledge test examiners may incur training costs in order to provide knowledge test exams to CLP applicants. To determine if this impact would be significant, FMCSA considers the impact as a percentage of annual revenue and estimates the impact to be significant if it surpasses one percent of revenue. For each knowledge test examiner, the knowledge tester would incur an opportunity cost of approximately $1,980 ($99 × 20 hours). The knowledge test examiner would need to have annual revenue below $198,000 ($1,980 ÷ 0.01) in order for this impact to reach the threshold of significance. Similarly, if a knowledge test examiner employed 10 affected employees, the annual opportunity cost would be $19,800 ($99 × 20 hours × 10 examiners) and would need to have annual revenue below $1.9 million in order for the impact to be considered significant. FMCSA considers it unlikely that a CDL knowledge tester would be able to operate with such low revenues, and as such does not anticipate that this rule would result in a significant impact on small CDL knowledge testers.

Motor carriers could experience opportunity cost savings if team drivers can work more efficiently when a driver with a CLP can operate the CMV after passing the skills test but before receiving the CDL credential. For example, a CDL holder could rest in the sleeper berth while the CLP driver with proof of a passing CDL skills test could operate the vehicle in a wage-earning capacity. FMCSA does not know how many CLP drivers pass their skills test but do not immediately receive their CDL credential, nor does FMCSA know the number of vehicle miles or trips that

[11] A *major rule* means any rule that OMB finds has resulted in or is likely to result in (a) an annual effect on the economy of $100 million or more; (b) a major increase in costs or prices for consumers, individual industries, geographic regions, Federal, State, or local government agencies; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (49 CFR 389.3).

[12] Public Law 104–121, 110 Stat. 857 (Mar. 29, 1996).

might be impacted by this rule. As such, FMCSA cannot estimate the cost savings that could result from this provision but anticipates that any cost savings would be below one percent of annual revenue for most motor carriers.

Therefore, I hereby certify that this rule will not have a significant impact on a substantial number of small entities.

E. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996,[13] FMCSA wants to assist small entities in understanding this proposed rule so they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman (Office of the National Ombudsman, see *https://www.sba.gov/about-sba/oversight-advocacy/office-national-ombudsman*) and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

F. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) requires Federal agencies to assess the effects of their discretionary regulatory actions. The Act addresses actions that may result in the expenditure by a State, local, or Tribal Government, in the aggregate, or by the private sector of $192 million (which is the value equivalent of $100 million in 1995, adjusted for inflation to 2022 levels) or more in any 1 year. Though this NPRM would not result in such an expenditure, and the analytical requirements of UMRA do not apply as a result, the Agency discusses the effects of this rule elsewhere in this preamble.

G. Paperwork Reduction Act

This proposed rule contains information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). As defined in 5 CFR 1320.3(c), *collection of information* comprises reporting, recordkeeping, monitoring, posting, labeling, and other similar actions. The title and description of the information collection, a description of those who must collect the information, and an estimate of the total annual burden follow. The estimate covers the time for reviewing instructions, searching existing sources of data, gathering and maintaining the data needed, and completing and reviewing the collection.

Title: Commercial Driver Licensing and Testing Standards.

OMB Control Number: 2126–0011.

Summary of the Information Collection: This is to request OMB's approval for the revision of the information collection titled ''Commercial Driver Licensing and Testing Standards,'' which is currently due to expire on April 30, 2025. This ICR is being updated to account for the proposed changes to regulatory requirements in the ''Amendments to the Commercial Driver's License Requirements; Increased Flexibility for Testing and for Drivers After Passing the Skills Test'' NPRM, as well as updated and more recent data that has become available following the approval of the current supporting statement. This current submission includes all information collection requirements contained in title 49 CFR part 383, titled ''Commercial Driver's License Standards; Requirements and Penalties'' and title 49 CFR part 384 titled, ''State Compliance with Commercial Driver's License Program.''

Need for Information: The licensed drivers in the United States deserve reasonable assurances that their fellow motorists are properly qualified to drive the vehicles they operate. In section 12005 of the CMVSA, the Secretary is required to develop minimum Federal standards for testing and licensing of operators of CMVs. Section 12007 of the Act also directed the Secretary, in cooperation with the States, to develop a clearinghouse to aid the States in implementing the one driver, one license, and one driving record requirement. This clearinghouse is known as CDLIS.

The CMVSA further required each person who has their CDL suspended, revoked, or canceled by a State, or who is disqualified from operating a CMV for any period, to notify his or her employer of such actions. Drivers of CMVs must notify their employers within 1 business day of being notified of the license suspension, revocation, and cancellation, or of the lost right to operate or disqualification. These requirements are reflected in 49 CFR part 383, titled ''Commercial Driver's License Standards; Requirements and Penalties.'' Specifically, § 383.21 prohibits a person from having more than one license; § 383.31 requires notification of convictions for driver violations; § 383.33 requires notification of driver's license suspensions; § 383.35 requires notification of previous employment; and § 383.37 outlines employer responsibilities. Section 383.111 requires the passing of a knowledge test by the driver and § 383.113 requires the passing of a skills test by the driver. Section 383.115 contains the requirement for the double/triple trailer endorsement; § 383.117 contains the requirement for the P endorsement; § 383.119 contains the requirement for the tank vehicle endorsement; and § 383.121 contains the requirement for the hazardous materials endorsement.

Currently, FMCSA is proposing to revise the regulations at 49 CFR 383 and 384 to increase flexibility for SDLAs and CDL applicants by: (1) removing the restriction allowing a State to administer the CDL skills test to a CLP holder who is domiciled in another State only if the applicant obtained training in the testing State; (2) permitting a CLP holder who has passed the CDL skills test to operate a CMV on public roads for purposes other than BTW training, provided the CLP holder has evidence of passing the CDL skills test and a qualified CDL holder is physically present in the CMV; (3) eliminating the requirement that an applicant wait at least 14 days to take the CDL skills test following initial issuance of the CLP; and (4) removing the requirement that CMV drivers must have a passenger (P) endorsement to transport CMVs designed to carry passengers, including school buses, when the vehicle is being transported in a driveaway-towaway operation and the vehicle is not carrying any passengers. Additionally, the NPRM proposes that third-party knowledge examiners be subject to the training, certification, and record check standards currently applicable to State knowledge examiners and the auditing and monitoring requirements now applicable to third-party skills testers.

[13] Public Law 104–121, 110 Stat. 857 (Mar. 29, 1996).

Proposed Use of Information: State officials use the information collected on the license application form (§ 383.71) that is posted to the CDLIS driver record, the information collected on the CLP application form that is posted to the CDLIS driver record (§ 383.71), and the conviction and disqualification data posted to the CDLIS driver record (§ 383.73) to prevent ineligible, not-qualified, and/or disqualified CLP and CDL holders and applicants from operating CMVs on the nation's highways. State officials are required to adopt and administer an FMCSA approved program for testing and ensuring the fitness of persons to operate a CMVs (§ 384.201). State officials are also required to administer knowledge and skills tests to CDL driver applicants (§ 384.202). The driver applicant is required to correctly answer at least 80 percent of the questions on each knowledge test in order to achieve a passing score on that test. To achieve a passing score on the skills test, the driver applicant must demonstrate that he/she can successfully perform all of the skills listed in the regulations. During State CDL compliance reviews, FMCSA officials review this information to ensure that the provisions of the regulations are being carried out. Without the aforementioned requirements, there would be no uniform control over driver licensing practices to prevent uncertified and/or disqualified drivers from being issued a CLP or CDL and to prevent unsafe drivers from spreading their convictions among several licenses in several States and remaining behind the wheel of a CMV. Failure to collect this information would render the regulations unenforceable.

Description of the Respondents: Drivers with a CLP or CDL and SDLAs.

Number of Respondents: 7,753,798 (7,712,074 CDL + 41,724 SDLAs).

Frequency of Response: Annual.

Burden of Response: 26,206,651 responses (7,925,642 CDL + 18,281,008 SDLAs). The associated cost burden is $103,725,614 ($71,424,225 CDL + $32,301,389 SDLAs).

Estimate of Total Annual Burden: 2,858,202 hours (2,067,271 CDL + 790,931 SDLAs).

In accordance with 44 U.S.C. 3507(d), FMCSA will submit the proposed information collection amendments to OIRA at OMB for its approval.

The Agency requests comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for FMCSA to perform its functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

H. E.O. 13132 (Federalism)

A rule has implications for federalism under section 1(a) of E.O. 13132 if it has ''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.'' FMCSA has determined that this rule would not have substantial direct costs on or for States, nor would it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. The changes proposed in the NPRM would increase flexibility for SDLAs in scheduling of CDL skills testing appointments and for States opting to offer CDL skills testing to out-of-State applicants. The NPRM could also reduce the number of P endorsements issued by the SDLAs. The proposed training, record check, and oversight requirements, currently applicable to States opting to rely on third-party skills testers, similarly would apply only to States choosing to permit third-party knowledge testing. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

I. Privacy

The Consolidated Appropriations Act, 2005,[14] requires the Agency to assess the privacy impact of a regulation that will affect the privacy of individuals. This NPRM would not require the collection of personally identifiable information (PII). The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program.

The E-Government Act of 2002,[15] requires Federal agencies to conduct a Privacy Impact Assessment (PIA) for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology would collect, maintain, or disseminate information as a result of this rule. Accordingly, FMCSA has not conducted a PIA.

In addition, the Agency submitted a Privacy Threshold Assessment (PTA) to evaluate the risks and effects the proposed rulemaking might have on collecting, storing, and sharing personally identifiable information. The Agency will complete a PTA to evaluate the risks and effects the proposed rulemaking might have on collecting, storing, and sharing personally identifiable information. The PTA has been submitted to FMCSA's Privacy Officer for review and preliminary adjudication and to DOT's Privacy Officer for review and final adjudication.

J. E.O. 13175 (Indian Tribal Governments)

This rule does not have Tribal implications under E.O. 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.

K. National Environmental Policy Act of 1969

FMCSA analyzed this proposed rule pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680), Appendix 2, paragraphs (6)(s)(6) and (7). The categorical exclusions (CEs) in paragraphs (6)(s)(6) and (7) cover requirements pertaining to providing knowledge and skills tests to qualified applicants for commercial drivers' licenses and requirements for State-issued commercial license documentation. The proposed requirements in this rule are covered by these CEs.

List of Subjects

49 CFR Part 383

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Penalties, Safety, Transportation.

49 CFR Part 384

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, Motor carriers.

[14] Public Law 108–447, 118 Stat. 2809, 3268, note following 5 U.S.C. 552a (Dec. 4, 2014).

[15] Public Law 107–347, sec. 208, 116 Stat. 2899, 2921 (Dec. 17, 2002).

Accordingly, FMCSA proposes to amend 49 CFR chapter III, parts 383 and 384 as follows:

PART 383—COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES

■ 1. The authority citation for part 383 continues to read as follows:

Authority: 49 U.S.C. 521, 31136, 31301 *et seq.,* and 31502; secs. 214 and 215 of Pub. L. 106–159, 113 Stat. 1748, 1766, 1767; sec. 1012(b) of Pub. L. 107–56, 115 Stat. 272, 297, sec. 4140 of Pub. L. 109–59, 119 Stat. 1144, 1746; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; sec. 23019 of Pub. L. 117–58, 135 Stat. 429, 777; and 49 CFR 1.87.

■ 2. Amend § 383.5 by:
■ a. Adding, in alphabetical order, definitions for *third-party knowledge examiner, third-party knowledge tester, and third-party skills tester;*
■ b. Adding a hyphen between the words ''third'' and ''party'' in the definition of *third party skills test examiner;* and
■ c. Removing the definition of *third party tester.*

The additions read as follows:

§ 383.5 Definitions.

* * * * *

Third-party knowledge examiner means a person employed by a third-party tester who is authorized by the State to administer the CDL knowledge tests specified in subparts G and H of this part.

Third-party knowledge tester means a person (including, but not limited to, another State, a motor carrier, a private driver training facility or other private institution, or a department, agency or instrumentality of a local government) authorized by the State to employ knowledge test examiners to administer the CDL knowledge tests specified in subparts G and H of this part.

* * * * *

Third-party skills tester means a person (including, but not limited to, another State, a motor carrier, a private driver training facility or other private institution, or a department, agency, or instrumentality of a local government) authorized by the State to employ skills test examiners to administer the CDL skills tests specified in subparts G and H of this part.

* * * * *

■ 3. Amend § 383.25 by:
■ a. Revising paragraph (a)(1); and
■ b. Removing paragraph (e).

The revision reads as follows:

§ 383.25 Commercial learner's permit (CLP).

(a) * * *

(1) The CLP holder is at all times accompanied by the holder of a valid CDL who has the proper CDL group and endorsement(s) necessary to operate the CMV. The CDL holder must at all times be physically present in the front seat of the vehicle next to the CLP holder or, in the case of a passenger vehicle, directly behind or in the first row behind the driver and must have the CLP holder under observation and direct supervision. *Exception:* A CLP holder who has passed the CDL skills test may operate a CMV on public roads or highways for purposes other than behind-the wheel training without the holder of a valid CDL of the proper class and with all proper endorsements being present in the front seat of the CMV or, in the case of a passenger vehicle, directly behind or in the first row behind the driver, provided the CDL holder is physically present elsewhere in the CMV. The CLP holder must also possess documentary evidence from the testing State (including a third-party skills tester authorized by the State) that they have passed the CDL skills test.

* * * * *

■ 4. Revise § 383.75 to read as follows:

§ 383.75 Third-party skills and knowledge testing.

(a) *Third-party skills tests.* A State may authorize a third-party tester to administer the skills tests as specified in subparts G and H of this part, if the following conditions are met:

(1) The skills tests given by the third-party are the same as those that would otherwise be given by the State using the same version of the skills tests, the same written instructions for test applicants, and the same scoring sheets as those prescribed in subparts G and H of this part.

(2) The State must conduct an on-site inspection of each third-party skills tester at least once every 2 years, with a focus on examiners with irregular results such as unusually high or low pass/fail rates.

(3) The State must issue the third-party tester a CDL skills testing certificate upon the execution of a third-party skills testing agreement.

(4) The State must issue each third-party CDL skills test examiner a skills testing certificate upon successful completion of a formal skills test examiner training course prescribed in § 384.228.

(5) The State must, at least once every 2 years, do one of the following for each third-party skills examiner:

(i) Have State employees covertly take the skills tests administered by the third-party as if the State employee were a test applicant;

(ii) Have State employees co-score along with the third-party examiner during CDL skills tests to compare pass/fail results; or

(iii) Re-test a sample of drivers who were examined by the third-party to compare pass/fail results.

(6) The State must take prompt and appropriate remedial action against a third-party skills tester that fails to comply with State or Federal standards for the CDL testing program, or with any other terms of the third-party contract.

(7) A skills test examiner who is also a skills instructor either as a part of a school, training program or otherwise is prohibited from administering a skills test to an applicant who received skills training by that skills test examiner.

(8) The State must revoke the skills testing certification of any examiner who does not conduct skills test examinations of at least 10 different applicants per calendar year. *Exception:* Examiners who do not meet the 10-test minimum must either take the refresher training specified in § 384.228 of this chapter or have a State examiner ride along to observe the third-party examiner successfully administer at least one skills test.

(9) The State has an agreement with the third-party tester containing, at a minimum, provisions that:

(i) Allow FMCSA, or its representative, and the State to conduct random examinations, inspections, and audits of its records, facilities, and operations without prior notice;

(ii) Require that all third-party skills test examiners meet the qualification and training standards of § 384.228;

(iii) Allow the State to do any of the following:

(A) Have State employees covertly take the skills tests administered by the third-party as if the State employee were a test applicant;

(B) Have State employees co-score along with the third-party examiner during CDL skills tests to compare pass/fail results; or

(C) Have the State re-test a sample of drivers who were examined by the third-party.

(iv) Reserve unto the State the right to take prompt and appropriate remedial action against a third-party skills tester that fails to comply with State or Federal standards for the CDL testing program, or with any other terms of the third-party contract;

(v) Require the third-party skills tester to initiate and maintain a bond in an amount determined by the State to be sufficient to pay for re-testing drivers in the event that the third-party or one or more of its examiners is involved in fraudulent activities related to

conducting skills testing of applicants for a CDL. *Exception:* A third-party tester that is a government entity is not required to maintain a bond;

(vi) Require the third-party tester to use only CDL skills examiners who have successfully completed a formal CDL skills test examiner training course as prescribed by the State and have been certified by the State as a CDL skills examiner qualified to administer CDL skills tests;

(vii) Require the third-party skills tester to use designated road test routes that have been approved by the State;

(viii) Require the third-party tester to submit a schedule of CDL skills testing appointments to the State no later than two business days prior to each test; and

(ix) Require the third-party skills tester to maintain copies of the following records at its principal place of business:

(A) A copy of the State certificate authorizing the third-party tester to administer a CDL skills testing program for the classes and types of commercial motor vehicles listed;

(B) A copy of each third-party examiner's State certificate authorizing the third-party examiner to administer CDL skills tests for the classes and types of commercial motor vehicles listed;

(C) A copy of the current third-party skills tester agreement;

(D) A copy of each completed CDL skills test scoring sheet for the current year and the past 2 calendar years;

(E) A copy of the third-party tester's State-approved road test route(s); and

(F) A copy of each third-party examiner's training record.

(x) Require the third-party tester to notify the State driver licensing agency through secure electronic means when a driver applicant passes skills tests administered by the third-party tester.

(b) *Third-party knowledge tests.* A State may authorize a third-party tester to administer the knowledge tests as specified in subparts G and H of this part, if the following conditions are met:

(1) The knowledge tests given by the third-party are the same as those that would otherwise be given by the State using the same version of the knowledge tests and the same written instructions for test applicants as prescribed in subparts G and H of this part. *Exception:* Knowledge tests given by a third-party knowledge examiner must be administered electronically;

(2) The State must conduct an on-site inspection of each third-party knowledge tester at least once every 2 years, with a focus on examiners with irregular results such as unusually high or low pass/fail rates;

(3) The State must issue the third-party knowledge tester a CDL knowledge testing certificate upon the execution of a third-party knowledge testing agreement;

(4) The State must issue each third-party CDL knowledge test examiner a knowledge testing certificate upon successful completion of a formal knowledge test examiner training course prescribed in § 384.228;

(5) The State must, at least once every 2 years, do one of the following for each third-party knowledge examiner:

(i) Have State employees covertly take the knowledge tests administered by the third-party as if the State employee were a test applicant;

(ii) Have State employees co-score along with the third-party examiner during CDL knowledge tests to compare pass/fail results; or

(iii) Re-test a sample of drivers who were examined by the third-party to compare pass/fail results.

(6) The State must take prompt and appropriate remedial action against a third-party knowledge tester that fails to comply with State or Federal standards for the CDL knowledge testing program, or with any other terms of the third-party contract;

(7) The State has an agreement with the third-party containing, at a minimum, provisions that:

(i) Allow FMCSA, or its representative, and the State to conduct random examinations, inspections, and audits of its records, facilities, and operations without prior notice;

(ii) Require that all third-party knowledge test examiners meet the qualification and training standards of § 384.228;

(iii) Allow the State to do any of the following:

(A) Have State employees covertly take the knowledge tests administered by the third-party as if the State employee were a test applicant;

(B) Have State employees co-score along with the third-party examiner during CDL knowledge tests to compare pass/fail results; or

(C) Have the State re-test a sample of drivers who were examined by the third-party.

(iv) Reserve unto the State the right to take prompt and appropriate remedial action against a third-party knowledge tester that fails to comply with State or Federal standards for the CDL knowledge testing program, or with any other terms of the third-party contract;

(v) Require the third-party knowledge tester to initiate and maintain a bond in an amount determined by the State to be sufficient to pay for re-testing drivers in the event that the third-party or one or more of its examiners is involved in fraudulent activities related to conducting skills testing of applicants for a CDL. *Exception:* A third-party tester that is a government entity is not required to maintain a bond;

(vi) Require the third-party tester to use only CDL knowledge examiners who have successfully completed a formal CDL knowledge test examiner training course as prescribed by the State and have been certified by the State as a CDL knowledge examiner qualified to administer CDL knowledge tests;

(vii) Require the third-party knowledge tester to notify the State driver licensing agency through secure electronic means when a driver applicant passes knowledge tests administered by the third-party tester; and

(viii) Require the third-party knowledge tester to maintain copies of the following records at its principal place of business:

(A) A copy of the State certificate authorizing the third-party tester to administer a CDL knowledge testing program for the classes and types of commercial motor vehicles listed;

(B) A copy of each third-party knowledge examiner's State certificate authorizing the third-party examiner to administer CDL knowledge tests for the classes and types of commercial motor vehicles listed;

(C) A copy of the current third-party knowledge testing agreement; and

(D) A copy of each third-party knowledge examiner's training record.

■ 5. Revise § 383.79(a)(1) to read as follows:

§ 383.79 Driving skills testing of out-of-State students; knowledge and driving skills testing of military personnel.

(a) * * *

(1) *State that administers the driving skills test.* A State may administer its driving skills test, in accordance with subparts F, G, and H of this part, to a person who is to be licensed in another United States jurisdiction (*i.e.,* State of domicile). Such test results must be transmitted electronically directly from the testing State to the licensing State in a direct, efficient, and secure manner.

* * * * *

■ 6. Add paragraph (d) to § 383.93 to read as follows:

§ 383.93 Endorsements.

* * * * *

(d) *Exception.* Operators are not required to obtain the passenger (P) endorsement to their CDL if the following conditions are met:

(1) A commercial motor vehicle designed to transport passengers,

including a school bus, is being transported from the manufacturer to a distributor or as part of a *driveaway-towaway* operation, as defined in § 390.5T of this subchapter; and

(2) The vehicle is empty of all passengers except the driver.

PART 384—STATE COMPLIANCE WITH COMMERCIAL DRIVER'S LICENSE PROGRAM

■ 7. The authority citation for part 384 continues to read as follows:

Authority: 49 U.S.C. 31136, 31301, *et seq.,* and 31502; secs. 103 and 215 of Pub. L. 106–159, 113 Stat. 1748, 1753, 1767; sec. 32934 of Pub. L. 112–141, 126 Stat. 405, 830; sec. 5524 of Pub. L. 114–94, 129 Stat. 1312, 1560; and 49 CFR 1.87.

■ 8. Revise § 384.228 to read as follows:

§ 384.228 Examiner training and record checks.

For all State and third-party CDL test examiners, the State must meet the following 10 requirements:

(a) Establish examiner training standards for initial and refresher training that provides CDL test examiners with a fundamental understanding of the objectives of the CDL testing program, and with all of the knowledge and skills necessary to serve as a CDL test examiner and assist jurisdictions in meeting the Federal CDL testing requirements.

(b) Require all State knowledge and skills test examiners to successfully complete a formal CDL test examiner training course and examination before certifying them to administer CDL knowledge and skills tests.

(c) The training course for CDL knowledge test examiners, including third-party knowledge test examiners, must cover at least the following three units of instruction:

(1) Introduction to CDL Licensing System:

(i) The Commercial Motor Vehicle Safety Act of 1986.

(ii) Drivers covered by CDL program.

(iii) CDL vehicle classification.

(iv) CDL endorsements and restrictions.

(2) Overview of the CDL tests:

(i) CDL test, classifications, and endorsements.

(ii) Different examinations.

(iii) Representative vehicles.

(iv) Validity and reliability.

(v) Test maintenance.

(3) Knowledge tests:

(i) General knowledge tests.

(ii) Specialized knowledge tests.

(iii) Selecting the appropriate tests and test forms.

(iv) Knowledge test administration.

(4) *Exception.* Current third-party skills testers who have maintained their CDL test examiner certification are not required to complete the units of instruction set forth in paragraphs (c)(1) and (2) of this section.

(d) The training course for CDL skills test examiners must cover at least the following five units of instruction:

(1) Introduction to CDL Licensing System:

(i) The Commercial Motor Vehicle Safety Act of 1986.

(ii) Drivers covered by CDL program.

(iii) CDL vehicle classification.

(iv) CDL endorsements and restrictions.

(2) Overview of the CDL tests:

(i) CDL test, classifications, and endorsements.

(ii) Different examinations.

(iii) Representative vehicles.

(iv) Validity and reliability.

(v) Test maintenance.

(3) Vehicle inspection test:

(i) Test overview.

(ii) Description of safety rules.

(iii) Test scoring procedures.

(iv) Scoring standards.

(v) Calculating final score.

(4) Basic control skills testing:

(i) Setting up the basic control skills course.

(ii) Description of safety rules.

(iii) General scoring procedures.

(iv) Administering the test.

(v) Calculating the score.

(5) Road test:

(i) Setting up the road test.

(ii) Required maneuvers.

(iii) Administering the road test.

(iv) Calculating the score.

(e) Require all third-party skills test examiners to successfully complete a formal CDL test examiner training course and examination before certifying them to administer CDL skills tests. The training course must cover at least the five units of instruction in paragraph (d) of this section.

(f) Require State and third-party CDL knowledge and skills test examiners to successfully complete a refresher training course and examination every 4 years to maintain their CDL test examiner certification. The refresher training course must cover at least the following:

(1) For CDL knowledge test examiners, including third-party knowledge test examiners, the three units of training described in paragraph (c) of this section.

(2) For CDL skills test examiners, the five units of training described in paragraph (d) of this section.

(3) Any State specific material and information related to administering CDL knowledge and skills tests.

(4) Any new Federal CDL regulations, updates to administering the tests, and new safety related equipment on the vehicles.

(g)(1) Complete nationwide criminal background check of all State and third-party test examiners at the time of hiring. *Exception.* For current third-party skills testers who have maintained their CDL test examiner certification and have already been subject to a nationwide criminal background check, a State is not required to complete the background check if the third-party skills test examiner also applies to become certified as a third-party knowledge test examiner.

(2) Complete nationwide criminal background check of any State and third-party current test examiner who has not had a nationwide criminal background check.

(3) Criteria for not passing the criminal background check must include at least the following:

(i) Any felony conviction within the last 10 years; or

(ii) Any conviction involving fraudulent activities.

(h) Maintain a record of the results of the criminal background check and CDL examiner test training and certification of all CDL test examiners.

(i) Rescind the certification to administer CDL tests of all test examiners who do not successfully complete the required refresher training every 4 years.

(j) The eight units of training described in paragraphs (c) and (d) of this section may be supplemented with State-specific material and information related to administering CDL knowledge and skills tests.

■ 9. Revise § 384.229 to read as follows:

§ 384.229 Skills and knowledge test examiner auditing and monitoring.

(a) To ensure the integrity of the CDL skills testing program, the State must:

(1) At least once every 2 years, conduct unannounced, on-site inspections of third-party testers' and examiners' records, including comparison of the CDL skills test results of applicants who are issued CDLs with the CDL scoring sheets that are maintained in the third-party testers' files;

(2) At least once every 2 years, conduct covert and overt monitoring of examinations performed by State and third-party CDL skills test examiners.

(3) Establish and maintain a database to track pass/fail rates of applicants tested by each State and third-party CDL skills test examiner, in order to focus covert and overt monitoring on examiners who have unusually high pass or failure rates;

(4) Establish and maintain a database of all third-party skills testers and examiners, which at a minimum tracks the dates and results of audits and monitoring actions by the State, the dates third-party skills testers were certified by the State, and name and identification number of each third-party CDL skills test examiner;

(5) Establish and maintain a database of all State CDL skills examiners, which at a minimum tracks the dates and results of monitoring action by the State, and the name and identification number of each State CDL skills examiner; and

(6) Establish and maintain a database that tracks skills tests administered by each State and third-party CDL skills test examiner's name and identification number.

(b) To ensure the integrity of the CDL knowledge testing program, the State must:

(1) At least once every 2 years, conduct unannounced, on-site inspections of third-party knowledge testers' and examiners' records;

(2) At least once every 2 years, conduct covert and overt monitoring of examinations performed by third-party CDL knowledge test examiners;

(3) Establish and maintain a database to track pass/fail rates of applicants tested by each third-party CDL knowledge test examiner, in order to focus covert and overt monitoring on examiners who have unusually high pass or failure rates;

(4) Establish and maintain a database of all third-party knowledge testers and examiners, which at a minimum tracks the dates and results of audits and monitoring actions by the State, the dates third-party knowledge testers were certified by the State, and name and identification number of each third-party CDL knowledge test examiner; and

(5) Establish and maintain a database that tracks knowledge tests administered by each State and the name and identification number of each third-party CDL knowledge test examiner.

Issued under authority delegated in 49 CFR 1.87.

Robin Hutcheson,

Administrator.

[FR Doc. 2024–01710 Filed 2–1–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 29

[Docket No. FWS–HQ–NWRS–2022–0106; FXRS12610900000–212–FF09R20000]

RIN 1018–BG78

National Wildlife Refuge System; Biological Integrity, Diversity, and Environmental Health

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; proposed policy updates.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose new regulations to ensure that the biological integrity, diversity, and environmental health (BIDEH) of the National Wildlife Refuge System (Refuge System) are maintained, and where appropriate, restored and enhanced, in accordance with the National Wildlife Refuge System Improvement Act of 1997. In addition, the Service is proposing updates to the existing BIDEH policy, which will be available for public comment concurrently with the proposed regulations in this docket. These proposed regulatory and policy revisions would support conservation throughout the Refuge System in response to both longstanding and contemporary conservation challenges, including the universal and profound effects of climate change on refuge species and ecosystems. Together, these proposals would uphold BIDEH across the Refuge System by providing refuge managers with a consistent approach for evaluating and implementing management actions to protect vulnerable species, restore and connect habitats, promote natural processes, sustain vital ecological functions, increase resilience, and adapt to climate change.

DATES: We will accept comments on the proposed rule and proposed revisions to the Service Manual chapter at 601 FW 3 that are received or postmarked on or before March 4, 2024.

ADDRESSES:

Document availability: This proposed rule and the draft Service Manual chapter 601 FW 3 are available at the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–HQ–NWRS–2022–0106, which is the docket number for this rulemaking. Then, click on the Search button. To access the Service Manual chapter, go to the tab for Supporting & Related Material.

Comment submission: You may submit comments on this proposed rule or the proposed revisions to 601 FW 3 by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–HQ–NWRS–2022–0106, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting screen, find the correct document and submit a comment by clicking on ''Comment.''
- *By hard copy:* Submit by U.S. mail or hand delivery to: Public Comments Processing, Attn: FWS–HQ–NWRS–2022–0106; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, MS: PRB (JAO/3W); Falls Church, VA 22041–3803.

We will not accept email or faxes. We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Request for Comments, below, for more information).

FOR FURTHER INFORMATION CONTACT: Katherine Harrigan, (703) 358–2440, *katherine_harrigan@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

In compliance with the Providing Accountability Through Transparency Act of 2023, please see docket FWS–HQ–NWRS–2022–0106 on *https://www.regulations.gov* for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:

Background

The National Wildlife Refuge System is the only network of Federal lands and waters in the United States dedicated to fish and wildlife conservation and, at more than 850 million acres, the largest system of its kind in the world. The National Wildlife Refuge System Administration Act of 1966 (Administration Act; 16 U.S.C. 668dd–668ee), as amended by the National Wildlife Refuge System Improvement Act of 1997 (Improvement Act; Pub. L. 105–57), is the primary statutory authority under which the Secretary of the Interior, acting through the Service, administers the Refuge System. The Alaska National Interest Lands Conservation Act of 1980 (16 U.S.C. 3111–3126), the Wilderness Act of 1964

(16 U.S.C. 1131–1136), and various other mandates also provide direction and authority for refuge management. The implementing regulations for Refuge System mandates are found in title 50 of the Code of Federal Regulations (CFR) at subchapter C.

The Improvement Act established the mission of the Refuge System to administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans. (16 U.S.C. 668dd(a)(2)). It set forth policy direction, management standards, and stewardship requirements for administering the more than 560 national wildlife refuges in the Refuge System, prioritizing conservation while ensuring public access to compatible, wildlife-dependent recreational opportunities and ensuring effective coordination with adjacent landowners and State fish and wildlife agencies. The law states that each refuge must be managed to fulfill both the Refuge System mission and the specific purposes for which that refuge was established. It additionally requires that, in administering the Refuge System, the Secretary shall ensure that the biological integrity, diversity, and environmental health of the Refuge System are maintained for the benefit of present and future generations of Americans. (16 U.S.C. 668dd(a)(4)(B)).

The Improvement Act is recognized as a visionary legislative charter for managing a system of wildlife reserves in part due to its mandate to ensure BIDEH. The terms comprising the BIDEH mandate are grounded in conservation biology and demonstrate congressional intent to conserve Refuge System fish, wildlife, plants, and habitats in accordance with the latest scientific understanding. This directive for a comprehensive, science-based approach to refuge management is critical to ensuring that imperiled species and diverse wildlife populations in North America are secure and thriving, sustained by a network of healthy lands and waters.

Need for New Regulations and Updated Policy

In 1998, the Service announced our intent to issue policy and regulations to administer the Improvement Act (63 FR 3583, January 23, 1998). In 2000, we published a draft policy on maintaining the ecological integrity of the Refuge System (65 FR 61356, October 17, 2000). After considering the comments received on the draft policy, the Service issued its BIDEH policy in 2001 (66 FR 3810, January 16, 2001). Included in the Service Manual at 601 FW 3, the policy provides internal guidance for agency implementation of the statutory requirements.

At the time the Service adopted the BIDEH policy, we did not promulgate BIDEH regulations as authorized in the Improvement Act. (See 16 U.S.C. 668dd(b)(5)). The Service did not anticipate the extent of climate change impacts on refuge species and habitats or the need to clarify in regulations our interpretation of and authority to implement the BIDEH mandate. However, in the nearly 25 years since enactment of the Improvement Act, refuges have begun to experience the effects of climate change while continuing to contend with the myriad of other anthropogenic stressors affecting fish, wildlife, plants, and their habitats. Climate change is transforming historical species composition and ecological function of habitats, creating new challenges to traditional wildlife management strategies that were based on stable, stationary baseline conditions. As the Refuge System becomes increasingly vital to addressing the dual threats of biodiversity loss and climate change, the Service recognizes the need to codify both existing and new practices for maintaining BIDEH to assist refuges in responding to these contemporary conservation challenges. Therefore, the Service has identified the need to propose new BIDEH regulations and updates to the existing BIDEH policy to accomplish these goals.

The purpose of this proposed rule and policy revision is to clarify the Service's authority to maintain the biological integrity, diversity, and environmental health of the Refuge System; ensure consistency in evaluating refuge management activities that affect BIDEH; and provide transparency in how we implement one of the most fundamental mandates in the laws governing the Refuge System. The proposed rule would codify longstanding refuge management principles and further empower refuge managers to uphold the Refuge System's conservation mission and achieve refuge purposes in the face of complex threats to wildlife and their habitat. The proposed policy revision would modernize the BIDEH policy and support the new regulations by providing further guidance for refuge managers to ensure the BIDEH of the Refuge System.

The Service currently operates and has always operated in accordance with the same Refuge System-wide principles for maintaining BIDEH represented in these proposed regulations and policy updates. However, the Service has determined that this proposed rule and policy revision is warranted to clarify Refuge System policies and practices; better prepare refuges to confront future impacts from climate change and other anthropogenic change; and provide the opportunity for public input on the Service's interpretation of the Improvement Act's BIDEH mandate, including its application in the context of predator control, conservation translocations, genetically engineered organisms, invasive species, pesticide use, agricultural practices, and mosquito control.

Proposed Additions to Existing Regulations

This proposed rule would amend the Refuge System regulations at 50 CFR subchapter C, part 29 (Land Use Management), subpart A (General Rules). The proposed regulatory changes would not modify any existing regulations but would add regulations regarding BIDEH at a new § 29.3.

Consistent with the Administration Act as amended by the Improvement Act, the Service is proposing regulations to ensure that the biological integrity, diversity, and environmental health of the Refuge System are maintained and, where necessary and appropriate, restored and enhanced. As shown in the rule portion of this document, the proposed regulations set forth an overarching statement in paragraph (a) describing what it means for the Service to ensure BIDEH; definitions for biological integrity, diversity, environmental health, and other key regulatory terms in paragraph (b); and overall directives for ensuring BIDEH on refuges in paragraph (c). Together these proposed regulations would provide a consistent framework within which refuge managers would consider potential management actions that may affect BIDEH. In addition, in paragraph (d), the proposed regulations also provide more specific direction for certain management activities that the Service has identified as having a particular propensity to affect BIDEH.

Notably, the proposed regulatory standard repeated throughout the regulations—requiring refuge managers to consider how management actions are necessary to meet statutory requirements, fulfill refuge purposes, and ensure BIDEH—flows directly from the Improvement Act. In the statute's requirements for administering the Refuge System, Congress elevated ensuring the maintenance of BIDEH to a similar level of importance as ensuring that the Refuge System mission and

refuge purposes are carried out, challenging the Service to implement these integral directives together to provide the greatest conservation benefits for fish and wildlife. (See 16 U.S.C. 668dd(a)(4)). The content of the proposed regulations and policy revision is further described below.

Proposed BIDEH Regulations and Accompanying Policy Updates

The Service is concurrently proposing updates to the BIDEH policy, 601 FW 3, which accord with and provide additional internal guidance for implementing the proposed regulations. We have decided to provide these documents for public comment concurrently because the proposed policy revision supplies further explanation for the application of the proposed regulations and therefore provides additional context for reviewing the proposed regulations.

Ensure Biological Integrity, Diversity, and Environmental Health

In § 29.3(a), the Service is proposing an overarching statement in support of the Refuge System's conservation mission defining what it means to ensure BIDEH on refuges, which is a concept integrated throughout the proposed BIDEH policy revision. The regulatory statement would promote management of the Refuge System as an interconnected network of lands and waters with functioning ecological processes to maintain the composition, activity, and resilience of the Refuge System over time. This concept means recognizing the Refuge System as an expansive complex of plant communities, habitats, and ecosystems representative of variable conditions and supporting a diversity of fish and wildlife, including viable populations of rare and imperiled species. This proposed regulation would codify the Service's continued commitment to managing refuge ecosystems holistically as components of larger landscapes and seascapes and supporting natural processes to meet our conservation goals, while also acknowledging that climate change and other anthropogenic change can require intervention to carry out the Refuge System mission and achieve refuge purposes. This commitment and acknowledgement are further distilled in the proposed policy updates.

The proposed regulatory statement includes a legal standard for managing refuges that would apply to each of the subsequent management directives and activities in the proposed rule when the Service refers to an action as being necessary to ensure BIDEH. This proposed legal standard would instruct refuge managers to use their sound professional judgment, informed by the best available scientific information, to ensure that management actions benefit wildlife conservation by contributing to, and not diminishing, BIDEH. The Service uses the term ''sound professional judgment'' as defined in the Improvement Act and existing Refuge System regulations, directing refuge managers to make their finding, determination, or decision to conduct an activity consistent with principles of sound fish and wildlife management and available science and resources, as well as their field experience and knowledge of the particular refuge's resources. This proposed requirement would foster defensible science-based management decisions, strengthen management actions that support ecological integrity, bolster decision making that avoids putting BIDEH at risk, and help prevent further degradation of environmental conditions on refuges. The proposed updates to the BIDEH policy would incorporate this legal standard throughout the policy revision as well.

Definitions

In both the new regulations and policy revision, the Service is proposing updated definitions for biological integrity, diversity, and environmental health based on definitions used in the Service's existing BIDEH policy, 601 FW 3, that were vetted through public notice and comment in 2000 and 2001 (66 FR 3810, January 16, 2001). The Service is proposing to revise these definitions to acknowledge that historical conditions may need to serve as a reference point, rather than an end goal, for managing refuges where climate change and other anthropogenic change are significantly altering ecosystems. This proposed language would untether current and future management actions from sustaining historical conditions that may no longer be possible on many refuges, while continuing to recognize the value of a contextual historical baseline for developing management goals. The Service also proposes to update the definitions by explicitly recognizing the impacts of climate change and other anthropogenic change on refuge ecosystems, which is critical to understanding the three BIDEH terms in their proper context, both now and in the future.

The Service is also including proposed definitions for other terms helpful to understanding the proposed regulations and policy. These terms all have established meanings either in wildlife biology, in existing Service policy, in other Federal law and policy, or in some combination of these. The Service has not departed from the accepted meanings in crafting these regulatory definitions, but we did find it necessary in the interest of greater clarity to tailor them to the BIDEH context. The proposed updates to the BIDEH policy also include some additional proposed definitions that would provide further context for the content expanding on the proposed regulations in the policy itself.

Management Directives for Ensuring Biological Integrity, Diversity, and Environmental Health

Proposed § 29.3(c) would include Refuge System-wide directives for maintaining BIDEH in refuge management. These directives—concerning universal concepts of climate, habitat, species, water, soil, and air—would create a framework within which refuge managers can determine and implement management activities. These fundamental directives are common to all refuges and would provide basic sideboards to guide management decisions consistent with other applicable law, regulation, and policy. They are central to the Service's ability to meet our statutory obligations and policy goals under the Improvement Act and are specifically relevant to fulfilling refuge purposes and ensuring BIDEH. The Service proposes further guidance for these management directives in section 3.10 of the proposed BIDEH policy accompanying these proposed regulations.

In the proposed regulation at paragraph (c)(1) and associated policy updates, the Service acknowledges that climate change and other anthropogenic change are affecting refuge fish, wildlife, plants, and habitats. The proposed language would direct refuge managers to address these threats through adaptation and mitigation strategies as necessary to meet statutory requirements, fulfill refuge purposes, and ensure BIDEH. This proposed regulation and accompanying policy revision recognize that climate change is a major driver in species decline and biodiversity loss, while ecosystem conservation can serve an essential role in both climate change mitigation and adaptation, as well as species survival and recovery. They would therefore allow refuge managers flexibility to implement a combination of responses to address climate change impacts and other anthropogenic stressors, providing discretion for managers to choose the most appropriate mitigation and adaptation strategies on a particular

refuge, so long as they meet the proposed regulatory standard.

The proposed regulation at paragraph (c)(2) and associated policy updates would prioritize deference to natural processes and support ecological connectivity as a means of achieving refuge habitat objectives and landscape planning goals. However, when natural processes are insufficient to meet refuge habitat objectives, the proposed language would direct managers to intervene with science-based management techniques that mimic natural processes in accordance with the proposed regulatory standard. Examples of such management techniques are provided in the accompanying policy. The proposed regulation and associated policy updates would also instruct managers to use such techniques and encourage establishment of wildlife corridors to facilitate adaptation to climate change and other stressors.

The proposed regulation at paragraph (c)(3) and associated policy updates would similarly codify the Service's ability to supplement natural processes to meet fish and wildlife population objectives, sustain ecosystems, and restore or recover imperiled species on refuges when habitat conditions and natural processes are insufficient. It would work in tandem with the regulation under proposed paragraph (c)(2) to prioritize deference to natural processes as the default for determining sustainable populations, while also providing flexibility to take actions to conserve and manage species when necessary to meet statutory requirements, fulfill refuge purposes, and ensure BIDEH. The associated policy updates provide examples of such supplemental management actions and guidance for maintaining native populations.

The regulation regarding refuge water rights at proposed paragraph (c)(4) stems directly from Improvement Act mandates, as reiterated in the associated policy updates. The proposed regulation and policy would incorporate these legal requirements, directing the Service to maintain and exercise refuge water rights in accordance with local, State, and Federal laws and to acquire, transfer, or lease water rights in accordance with the proposed regulatory standard. The proposed policy updates would provide substantive guidance for refuge managers to follow to uphold refuge water rights and would further empower them to pursue and secure critical water assets to support the myriad of migratory birds, fish, and other wildlife that rely on refuge habitats.

Finally, the proposed regulation at paragraph (c)(5) and associated policy updates would direct refuge managers to promote and maintain soil health and air quality as other abiotic components vital for sustaining and restoring refuge habitats in addition to water quantity and quality. The regulation would instruct the Service to conserve and manage these essential resources within our jurisdiction in accordance with the regulatory standard and address threats to them through appropriate management actions. The proposed policy updates provide additional guidance to explain how refuge managers would maintain these foundational resources to support healthy ecosystems and ensure the BIDEH of the Refuge System.

Management Activities and Uses for Ensuring Biological Integrity, Diversity, and Environmental Health

The regulations in proposed § 29.3(d) would guide specific management activities and uses that can especially influence BIDEH, including predator control, conservation translocations, use of genetically engineered organisms, invasive species management, pesticide use, agricultural uses, and mosquito control. These proposed regulations are not intended to cover the range of management practices conducted on refuges that may affect BIDEH. Rather, the Service carefully selected these topics to codify and clarify our existing policies regarding these management activities and uses, improve our ability to respond to climate change and other anthropogenic factors, and empower refuge managers to consistently analyze and apply these tools—or refrain from applying them—as appropriate, to better support BIDEH. The Service proposes further guidance for these management activities and uses in section 3.13 of the proposed BIDEH policy accompanying these proposed regulations.

The management activities and uses included in these proposed regulations and associated policy updates would be implemented on Refuge System habitats in conformance with the overall management directives in proposed § 29.3(c) and section 3.10 of the policy. This would mean that these activities and uses are all subject to the underlying conservation principle that defers to natural processes and favors management that mimics natural processes. When natural processes alone are insufficient to support ecological functions, refuge managers would be required to evaluate the necessity for and potential environmental effects of a proposed management activity or use in accordance with the National Environmental Policy Act (NEPA) before authorizing it, including considering reasonable alternatives, scientific support, and potential risk of unintended consequences. This approach is consistent with current Service policies.

Additionally, while each of the regulations in proposed paragraphs (d)(1)–(7) would direct a default position regarding use of a particular management practice, they simultaneously would provide flexibility to implement them as conservation tools when determined, based on comprehensive analysis, that they are necessary to meet statutory requirements, fulfill refuge purposes, and ensure BIDEH. Notably, NEPA analysis of management activities and uses could occur as part of development of a refuge's comprehensive conservation plan (CCP) or other approved management plan or could be conducted as a standalone analysis. Regardless, such activities and uses must be consistent with the CCP. Refuge managers must also fulfill other policy and legal requirements prior to implementing a management activity or use when applicable. This could include conducting scientific peer review (see section 3.14(C) of the proposed policy for more information on peer review requirements) or conducting a compatibility determination for refuge management economic activities or activities that involve use of a refuge by the public or other non-Refuge System entity (see the Service's Compatibility policy at 603 FW 2 and regulations at 50 CFR parts 25, 26, and 29 for more information). See the proposed regulations and associated policy updates for further substantive details and instruction for the management activities and uses contained in this proposed rule and policy revision.

Coordination With Adjacent Landowners, State and Tribal Partners

The Service recognizes that ensuring the BIDEH of the Refuge System necessitates a landscape-level perspective for managing an interconnected network of lands and waters involving collaboration with our State and Tribal partners, adjacent landowners, and other stakeholders. These proposed regulations and policy updates comply with and incorporate the Service's commitment to cooperate and coordinate with State partners, as appropriate, in accordance with 43 CFR 24.4(e) and 601 FW 7. They also encourage effective interaction and coordination with other owners of land adjoining refuges. The proposed

regulations and policy updates additionally comply with and uphold the Service's continued commitment to cooperate and coordinate with federally recognized Tribes and other Indigenous Peoples, consistent with the Service's Native American Policy at 510 FW 1, to protect treaty, religious, subsistence, and cultural interests in the Refuge System. Further, the Service proposes to identify and define Indigenous Knowledge in the policy updates as an appropriate source of historical information that would support best available scientific information about historical conditions as a reference point for management decisions.

Request for Comments

You may submit comments and materials on this proposed rule by either one of the methods listed in **ADDRESSES**. We will not accept comments sent by email or fax or to an address not listed in **ADDRESSES**. We will not consider comments that are not postmarked by the date specified in **DATES**.

We will post your entire comment on *https://www.regulations.gov.* Before including personal identifying information in your comment, you should be aware that we may make your entire comment—including your personal identifying information—publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *https://www.regulations.gov.*

Required Determinations

Clarity of This Proposed Rule

Executive Orders 12866 and 12988 and the Presidential Memorandum of June 1, 1998, require us to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

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

Regulatory Planning and Review (Executive Orders 12866, 13563, and 14094)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this proposed rulemaking action is not significant. The proposed rule would simply serve to codify longstanding refuge management principles and further empower refuge managers to uphold the Refuge System's conservation mission and achieve refuge purposes in the face of complex threats to wildlife and their habitat.

Executive Order 14094 reaffirms the principles of E.O. 12866 and E.O 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act [SBREFA] of 1996) (5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for ''significant impact'' and a threshold for a ''substantial number of small entities.'' See 5 U.S.C. 605(b). The SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

This proposed rule would govern the actions taken by the Service but would not create any requirements for or place any regulatory compliance burden on private entities. The Service also does not anticipate the requirements to promote BIDEH to alter the current practices of the Service's cooperative agriculture and water rights programs. The Service currently operates and has always operated in accordance with the same Refuge System-wide principles for maintaining BIDEH represented in these proposed regulations. The Service has determined that this proposed rulemaking is warranted to clarify our policies and practices, better prepare refuges to confront future impacts from climate change and other anthropogenic change, and provide the opportunity for public input on our interpretation of the Improvement Act's BIDEH mandate, including its application in the context of predator control, species introductions, genetically engineered organisms, invasive species, pesticide use, agricultural practices, and mosquito control. As a result of the internal nature of these proposed regulations, this rulemaking action would have no impact on small entities.

Therefore, the Service certifies that this rule, as proposed, would not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). A regulatory flexibility analysis is not required. Accordingly, a small entity compliance guide is not required.

Congressional Review Act

The proposed rule is not a major rule under 5 U.S.C. 804(2). The Service anticipates no significant employment or small business effects. This proposed rule:

a. Would not have an annual effect on the economy of $100 million or more.

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

c. Would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Unfunded Mandates Reform Act

Since this proposed rule would apply to management of refuges by the Service, it would not impose an

unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year. The proposed rule would not have a significant or unique effect on State, local, or Tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (E.O. 12630)

In accordance with E.O. 12630, this proposed rule would not have significant takings implications. This proposed rule would affect only management of refuges by the Service.

Federalism (E.O. 13132)

As discussed under *Regulatory Planning and Review* and *Unfunded Mandates Reform Act,* above, this proposed rule would not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement under E.O. 13132.

Civil Justice Reform (E.O. 12988)

In accordance with E.O. 12988, the Department of the Interior has determined that this proposed rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the E.O.

Energy Supply, Distribution or Use (E.O. 13211)

E.O. 13211 requires agencies to prepare statements of energy effects for regulations that significantly affect energy supply, distribution, and use. Because this proposed rule would uphold and enforce existing management principles and practices by the Service on refuges, it is not a significant regulatory action under E.O. 12866, and we do not expect it to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no statement of energy effects is required.

Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

In accordance with E.O. 13175, the Service has evaluated possible effects on federally recognized Indian Tribes and has determined that there are no effects. Before taking actions, the Service coordinates our activities on Service lands and waters with Tribal governments having adjoining or overlapping jurisdiction.

Paperwork Reduction Act of 1995 (PRA)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. The Service may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

The Service is required under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) to assess the impact of any Federal action significantly affecting the quality of the human environment, health, and safety. The Service has determined that this proposed rule falls under the class of actions covered by the following Department of the Interior categorical exclusion: Policies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature; or whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis and will later be subject to the NEPA process, either collectively or case-by-case (43 CFR 46.210(i)). Under the proposed rule, the Service would take future actions guided by the requirements to support BIDEH, but these future actions would be determined and taken at the individual refuge level and their environmental impacts assessed on a case-by-case basis. Therefore, the environmental impacts of the proposed rule are too speculative to lead to meaningful analysis at this time. The Service would assess the environmental impact of any potential management action mentioned in these regulations prior to taking that action on Service lands or waters.

Primary Author

Katherine Harrigan, Division of Natural Resources and Conservation Planning, National Wildlife Refuge System, is the primary author of this proposed rulemaking document.

List of Subjects in 50 CFR Part 29

Public lands mineral resources, Public lands rights-of-way, Wildlife refuges.

Proposed Regulation Promulgation

For the reasons set forth in the preamble, we propose to amend part 29, subchapter C of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 29—LAND USE MANAGEMENT

■ 1. The authority citation for part 29 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd, 685, 690d, 715i, 725, 3161; 30 U.S.C. 185; 31 U.S.C. 3711, 9701; 40 U.S.C. 319; 43 U.S.C. 315a; 113 Stat. 1501A–140.

■ 2. Add § 29.3 to read as follows:

§ 29.3 Biological integrity, diversity, and environmental health.

We will maintain and, where necessary and appropriate, restore and enhance the biological integrity, diversity, and environmental health of national wildlife refuges, both individually and as a network of intact, functioning, and resilient habitats for fish, wildlife, and plants, for the benefit of present and future generations of Americans.

(a) *Ensure biological integrity, diversity, and environmental health.* To ensure biological integrity, diversity, and environmental health means to holistically conserve refuge ecosystems and all their components and processes across multiple spatial scales; promote natural processes; and address ecological transformation caused by climate change and other anthropogenic change to accomplish the mission of the National Wildlife Refuge System (Refuge System). We will seek to achieve the highest measure of biological integrity, diversity, and environmental health on refuges, which is represented by diverse, functioning, and self-sustaining ecosystems that are resilient to emerging or future conditions. We will use sound professional judgment, informed by the best available scientific information, to ensure that refuge management contributes to and does not diminish the biological integrity, diversity, and environmental health of refuges and the Refuge System for the benefit of fish and wildlife conservation.

(b) *Definitions.* In addition to relevant definitions in § 25.12 of this subchapter C, the following definitions apply to this section:

Adaptation means an adjustment in natural or human systems to a new or changing environment that uses beneficial opportunities or moderates negative effects.

Anthropogenic change means environmental change that humans cause or influence, either directly or indirectly.

Biological integrity means the capacity of an ecological system to support and maintain a full range of biotic composition, structure, function, and processes over time that exhibit diversity, connectivity, and resilience at genetic, organism, population, and community levels. We evaluate biological integrity by referencing historical conditions, recognizing that

climate change and other anthropogenic change are influencing refuge ecosystems.

Climate change mitigation means measures taken to reduce the amount and speed of future climate change by reducing emissions of heat-trapping gases or removing carbon dioxide from the atmosphere, including by improving ecosystem capacity for biological carbon sequestration.

Connectivity means the degree to which landscapes, waterscapes, and seascapes allow species to move freely and ecological processes to function unimpeded.

Conservation translocation means deliberately moving organisms from one site to another for release, with the intention of yielding a measurable conservation benefit at the levels of a population, species, or ecosystem.

Diversity means the variety of life and its processes, including the richness and abundance of living organisms, the genetic differences among them, and communities and ecosystems in which they occur. We evaluate diversity by referencing historical conditions, recognizing that climate change and other anthropogenic change are influencing refuge ecosystems.

Ecological transformation means the shift in an ecosystem, resulting in a new system that deviates from prior ecosystem structure and function or species composition.

Ecosystem means systems comprised of biota (living organisms), the abiotic environment (*e.g.,* air, light, soils, water), the interactions within and between them, and the physical space in which they operate.

Environmental change means an alteration or disturbance of the environment caused by humans or natural processes that generates differences in the function or characteristics of an ecosystem.

Environmental health means composition, structure, and functioning of soil, water, air, and other abiotic features, including the abiotic processes that shape the environment. We evaluate environmental health by referencing historical conditions, recognizing that climate change and other anthropogenic change are influencing refuge ecosystems.

Historical conditions means composition, structure, and function of ecosystems that existed prior to ecological degradation caused by anthropogenic change, based on best available scientific and historical information.

Invasive species means with respect to a particular ecosystem a non-native organism, including its seeds, eggs, spores, or other biological material capable of propagating that species, whose introduction causes or is likely to cause economic or environmental harm, or harm to human, animal, or plant health.

Native means with respect to a particular ecosystem, a species that, other than as a result of an introduction, historically occurred or currently occurs in that ecosystem, including when such a species expands or shifts its range as a result of natural processes in response to environmental change.

Natural processes mean interactions among plants, animals, and the environment that occur without substantial human influence.

Predator control means actions or programs with the intent or potential to alter predator-prey population dynamics on a refuge by reducing a population of native predators through lethal or nonlethal methods, except for actions necessary to protect public health and safety and those enumerated under paragraph (d)(1) of this section.

(c) *Management directives for ensuring biological integrity, diversity, and environmental health.* The following regulations serve as a framework for determining and implementing refuge management actions to meet our statutory obligations and policy goals:

(1) *Address climate change.* Within the Refuge System, we will manage species and habitats affected by climate change and other anthropogenic change by using climate change mitigation and adaptation strategies when necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health.

(2) *Conserve and connect habitat.* We allow for and defer to natural processes on habitats within the Refuge System and promote conservation, restoration, and connectivity to meet refuge habitat objectives and landscape planning goals. We will avoid and minimize habitat fragmentation to sustain biological integrity and diversity. When natural processes cannot meet habitat objectives or facilitate adaptation to anthropogenic change, we will use science-based management techniques or acquire lands when necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health.

(3) *Manage fish and wildlife populations.* We conserve fish and wildlife populations within the Refuge System to meet refuge population objectives, sustain functioning ecosystems, and, where appropriate, restore or recover imperiled species. When habitat conditions and natural processes are insufficient to meet these goals or facilitate adaptation to anthropogenic change, we may pursue actions to supplement natural processes when necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health.

(4) *Uphold water rights.* We will maintain and exercise our water rights on habitats within the Refuge System in accordance with local, State, and Federal laws. Where necessary, we will acquire, transfer, or lease water rights to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health.

(5) *Promote and maintain healthy soil, water, and air.* We promote and maintain soil health, water quality and quantity, and air quality as vital to sustaining and restoring habitats within the Refuge System through conservation and management to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health. We will address threats to these abiotic components by pursuing appropriate actions, including when such threats to refuge resources arise outside refuge boundaries.

(d) *Management activities and uses with potential to ensure biological integrity, diversity, and environmental health.* The regulations in this paragraph (d) provide guidance for certain management activities and uses that may support the maintenance of biological integrity, diversity, and environmental health. These activities and uses will be implemented within the Refuge System only as consistent with the management directives set forth in paragraph (c) of this section. Proposed activities and uses will be evaluated in compliance with the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and other legal requirements, as applicable.

(1) *Native predator control.* We prohibit predator control unless it is determined necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health. We may implement lethal predator control only when all other feasible methods have been fully evaluated and such control is considered the only practical means of addressing a specific, significant conservation concern and ensuring biological integrity, diversity, and environmental health. We do not consider the following actions to be predator control:

(i) Agency removal of native predator(s) solely to protect public health and safety;

(ii) Use of barriers or nonlethal deterrents to protect the public, property, or vulnerable species, but that are not intended to reduce native predator populations;

(iii) Compatible, refuge-approved taking of fish and wildlife for subsistence uses under Federal or State subsistence regulations that do not compromise maintaining biological integrity, diversity, and environmental health on the refuge;

(iv) Compatible, refuge-approved recreational hunting and fishing opportunities that do not compromise maintaining biological integrity, diversity, and environmental health on the refuge; and

(v) Removal of invasive species.

(2) *Conservation translocations.* We may allow the introduction of a species outside its current range to avoid extinction or extirpation; restore a species; reestablish a specific ecological function lost to extinction or extirpation; or, in accordance with § 17.81(a) of this chapter, when necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health.

(3) *Use of genetically engineered organisms.* We prohibit the use of genetically engineered organisms unless their use is determined necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health.

(4) *Invasive species management.* We pursue actions to control invasive species as part of an integrated pest management plan when necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health.

(5) *Pesticide use.* We may allow the use of pesticides, following review and approval of their use as part of an integrated pest management plan, when necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health. Such use must not result in adverse effects on populations of nontarget species.

(6) *Agricultural uses.* We prohibit the use of agricultural practices unless they are determined necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health, and where we cannot achieve refuge management objectives through natural processes.

(7) *Mosquito control.* We prohibit control of native mosquitoes unless it is determined necessary to meet statutory requirements, fulfill refuge purposes, and ensure biological integrity, diversity, and environmental health or protect human health and safety. In these situations, chosen control methods must be the least injurious to fish, wildlife, and their habitats. We may coordinate with public health agencies or mosquito control organizations to implement the most effective control methods that minimize risk to refuge ecosystems and public health.

Shannon Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2024–02076 Filed 2–1–24; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 89, No. 23
Friday, February 2, 2024

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

Agricultural Marketing Service

[Doc. No. AMS–TM–23–0076]

Notice of Availability of the Final Programmatic Environmental Assessment and Finding of No Significant Impact for the AMS Organic Market Development Grant Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Agricultural Marketing Service (AMS) announces the availability of the Final Programmatic Environmental Assessment (PEA) and Finding of No Significant Impact (FONSI) for the AMS Organic Market Development Grant Program.

FOR FURTHER INFORMATION CONTACT: Betsy Rakola, Associate Deputy Administrator, Transportation and Marketing Program; Telephone: (202) 690–1300; Email: *OMDG@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Final PEA and FONSI analyze and disclose the potential environmental impacts associated with the establishment of the Organic Market Development Grant Program (OMDG). AMS has proposed to fund grants to support the development of new and expanded organic markets by providing additional resources for businesses transitioning to organic or initiating new organic production and processing capacity. These grants will create new and improved markets for domestically produced organic products through investments in expanded certified organic processing capacity; activities that develop, maintain, or expand commercial organic markets; and organic product developments which create new uses for producers that currently lack markets.

Selected applicants for the OMDG program may invest in certified organic infrastructure and expand processing capacities, in addition to adding manufacturing, storing, transporting, wholesaling, or distribution infrastructure. Funded activities will include developing new markets to increase demand for domestically produced organic agricultural products and providing additional market networks.

The OMDG Program is authorized by authorized by section 5(e) of the Commodity Credit Corporation (CCC) Charter Act, (15 U.S.C. 714(e)). Section 5(e), as amended, authorizes USDA (through the CCC) to ''increase the domestic consumption of agricultural commodities (other than tobacco) by expanding or aiding in the expansion of domestic markets or by developing or aiding in the development of new and additional markets, marketing facilities, and uses for such commodities.'' Recipients of funding from this proposed program would be allowed 36 months to complete work funded by the grant awards.

The environmental impacts of funding projects to enhance existing organic processing facilities have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA) of 1969, Public Law 91–190, 42 U.S.C. 4321–4347, as amended.

A Final PEA and FONSI have been prepared, and based on this analysis, AMS has determined there will not be a significant impact to the human environment. As a result, an Environmental Impact Statement (EIS) has not been initiated (40 CFR 1501.6). AMS intends for this PEA to create efficiencies by establishing a framework that can be used for ''tiering,'' where appropriate, to project-specific actions that require additional analysis. As decisions on specific applications are made, to the extent additional NEPA analysis is required, environmental review will be conducted to supplement the analysis set forth in this PEA.

The Final PEA and FONSI are available for review online at the program website: *https://www.ams.usda.gov/services/grants/omdg.*

Comments

AMS published a Draft PEA for public comment on November 20, 2023. The public comment period ended on December 20, 2023. No comments were received during the designated timeframe, and as such, no substantial changes were made to the document.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–02120 Filed 2–1–24; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–LP–23–0027]

Soybean Promotion, Research, and Information Program: Opportunity To Request a Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) announces that soybean producers may request a referendum to determine if producers want the Secretary to conduct a referendum on the Soybean Promotion and Research Order (Order), as authorized under the Soybean Promotion, Research, and Consumer Information Act (Act). Participation in the Request for Referendum is voluntary. Producers should participate only if they wish to request a referendum on the program. If at least 10 percent (not in excess of one-fifth of which may be producers in any one State) of the 413,358 eligible producers, as determined by the U.S. Department of Agriculture (USDA), participate in the Request for Referendum, a referendum would be held within 1 year from that determination. If results of the Request for Referendum indicate that a referendum is not supported, a referendum would not be conducted. The results of the Request for Referendum will be published in a notice in the **Federal Register**.

DATES: Soybean producers may request a referendum during a 4-week period beginning on May 6, 2024, and ending May 31, 2024. To be eligible to participate in the Request for Referendum, producers must certify that they or the producer entity they are authorized to represent paid an assessment at any time between January 1, 2022, and December 31, 2023.

ADDRESSES: Form LP–51–1, Soybean Promotion and Research Order Request for Referendum, may be obtained by mail, fax, or in person from the Farm Service Agency (FSA) county offices from May 6, 2024, to May 31, 2024. Form LP–51–1 may also be obtained via the internet at *https://www.ams.usda.gov/rules-regulations/research-promotion/soybean* during the same time period. Completed forms and supporting documentation must be returned to the appropriate county FSA office by fax or in person no later than close of business May 31, 2024, or if returned by mail, must be postmarked by midnight May 31, 2024, and received in the county FSA office by close of business on June 7, 2024.

FOR FURTHER INFORMATION CONTACT: Jason Julian, Agricultural Marketing Specialist, Research and Promotion Division, Livestock and Poultry Program, AMS, USDA, STOP 0249, 1400 Independence Avenue SW, Washington, DC 20250–0249; Telephone (202) 720–5705; or Email to *Jason.Julian@usda.gov;* or contact a local FSA Office; the phone numbers, fax numbers, and mailing addresses can be found at *https://www.farmers.gov/.*

SUPPLEMENTARY INFORMATION: In accordance with the Act (7 U.S.C. 6301–6311), this notice announces the dates when the Request for Referendum will be conducted and the place where soybean producers may request a referendum on the Order (7 CFR part 1220). The Act provides that the Secretary, 5 years after the conduct of the initial referendum and every 5 years thereafter, shall give soybean producers an opportunity to request a referendum on the Order. The initial referendum was held in February 1994, and the results were announced on April 1, 1994. During the initial referendum, 85,606 valid ballots were cast, with 46,060 (53.8 percent) in favor of continuing the Order and 39,546 votes (46.2 percent) against continuing the Order. The Act required approval by a simple majority for the Order to continue.

The most recent opportunity for producers to request a referendum on the Order was in May 2019. During that period, 708 producers completed valid requests—short of the 51,501 required to trigger a referendum. On July 17, 2019, USDA announced the results of the Request for Referendum and that the requisite number of producers had not requested that a referendum be conducted.

Eligibility

To be eligible to participate, soybean producers must certify that they or the entity they are authorized to represent paid an assessment under the Soybean Checkoff Program at sometime between January 1, 2022, and December 31, 2023. They must complete and submit Form LP–51–1—Soybean Promotion and Research Order Request for Referendum, in person; by mail, postmarked by May 31, 2024, and received no later than June 7, 2024; or by fax between May 6, 2024, and May 31, 2024. Individual producers and other producer entities would request a referendum at the county FSA office where FSA maintains and processes the producer's, corporation's, or other entity's administrative farm records. For the producer, corporation, or other entity not participating in FSA programs, the opportunity to request a referendum would be provided at the county FSA office serving the county where the producer, corporation, or other entity owns or rents land. Form LP–51–1 may also be obtained via the internet at *https://www.ams.usda.gov/rules-regulations/research-promotion/soybean*. If obtained by the internet, Form LP–51–1 must be completed and returned by mail, fax, or in person with the supporting documentation to the county FSA office where FSA maintains and processes the producer's, corporation's, or other entity's administrative farm records.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), the information collection requirements connected with the Request for Referendum have been approved by the Office of Management and Budget (OMB) and assigned OMB control number 0581–0093.

Authority: 7 U.S.C. 6301–6311.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–02136 Filed 2–1–24; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Notice of Request for Approval of an Information Collection

AGENCY: Office of the Chief Economist, Office of Pest Management Policy, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of USDA's Office of Pest Management Policy to request renewal of an existing information collection for Multiple Crop and Pesticide Use Surveys.

DATES: Comments on this notice must be received by April 2, 2024 to be assured of consideration.

ADDRESSES: USDA invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *https://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Office of Pest Management Policy, 1400 Independence Ave. SW, Room3871—South Building, Mailstop 3817, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Ave. SW, Room4054—South Building, Washington, DC 20250–3700. You may also want to send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Michelle Ranville, Office of the Chief Economist, Office of Pest Management Policy, U.S. Department of Agriculture, 1400 Independence Ave. SW, Washington, DC 20250–3700, (202) 577–1980.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance to Conduct Multiple Crop and Pesticide Use Surveys.

OMB Number: 0503–0026.

Expiration Date of Approval: Three years from approval date.

Type of Request: Renewal and revision of a currently approved information collection.

Abstract: The Office of Pest Management Policy (OPMP) of the United States Department of Agriculture (USDA) requests approval from the Office of Management and Budget (OMB) for generic clearance that will allow OPMP to collect information from

agricultural entities. The primary purpose of this information will be to support OPMP's understanding of agricultural practices pertaining to pest management. OPMP is undertaking this effort to satisfy legislative requirements outlined in Title X, Section 10109 of the 2018 Farm Bill, which mandates that The Secretary of Agriculture, acting through the Office of the Chief Economist's Director of OPMP, collect this information.

Pest management information is critical to supporting a key responsibility of OPMP, *i.e.,* to ''consult with agricultural producers that may be affected by pest management or pesticide-related activities or actions of the Department or other agencies,'' as outlined in the Agricultural Research, Extension, and Education Reform Act of 1998. The information collected under this approval improves OPMP's ability to better understand the utilization of pest management tools by agricultural producers via input from producers and pest management advisors, including extension experts and crop consultants, who in addition to being advisors are often agricultural producers themselves. Data collected are intended to capture agricultural practices and needs to support federal activities that pertain to pest management, which are typically time-sensitive and necessitate the need for rapid data collection.

In most cases, the turnaround time for these information collections will be a function of 60-day public comment periods associated with pesticide licensing actions, making it essential for OPMP to promptly administer requests and collect responses. Various factors drive what types of questions OPMP may ask, including the active ingredient, crop, region, application method, and specific target pest problems. Examples of questions include inquiries regarding pesticide usage, the availability and comparative utility of alternative pest management tactics for target pests, the feasibility of pesticide mitigations, and resistance management concerns. Further, OPMP often needs to understand niche pest situations on specific crops and/or regions, which typically is not information that is readily available from other sources.

This effort does not intend to duplicate information collection activities administered by USDA's National Agricultural Statistics Service (NASS) that pertain to pest management. When needed data are current and available through NASS collection efforts, it is OPMP's policy to utilize and recognize such information as Best Available Data.

These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113) and Office of Management and Budget regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995).

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 15 minutes per response. Outside of upfront demographic questions, no more than fifteen questions will be asked per response.

Type of Respondents: American Society of Agronomy (ASA) Certified Crop Advisors (CCAs); crop consultants associated with the National Alliance of Independent Crop Consultants (NAICC); county extension agents affiliated with the National Association of County Agricultural Agents (NACAA); other agricultural stakeholders, such as farmers, ranchers, nursery operators, animal operations (cattle, chickens, catfish, etc.), foresters, beekeepers, farm managers, farm contractors, extermination and pest control operators, postharvest crop packing and/or processing activities, cotton ginning, etc.; university agricultural academics/experts (other than those represented through NACAA); and/or other specialists that work with or on behalf of these groups.

Estimated Number of Respondents: Given that it is impossible to predict the number of impactful federal actions that pertain to pest management in any given year, the entire universe of specialists employed in the areas outlined above could be considered as possible respondents. Realistically, however, only a small subset of these individuals is expected to respond to a request. Using estimates provided by the ASA, the NAICC, and the NACAA, as of November 2023 there were 10,720 CCAs in the United States, 604 NAICC independent crop consultants, and 3,259 agricultural experts affiliated with the NACAA. Although some individuals are both CCAs and independent crop consultants, at most the total universe of crop advisors/consultants is 14,583 respondents. OPMP adds 1,000 to this number to account for outreach to smaller stakeholder groups for knowledge/information on pest management that may not be readily available from crop consultants (*e.g.,* pest management in packing houses, commercial seed treatment practices, etc.). On the first iteration of this ICR, NASS survey methodologists estimated a response rate of 15% should be expected until further empirical data is available. OPMP has retained this estimate for the revision of this ICR. This could lead to a maximum number of 2,338 total respondents per survey. Potential respondents will be contacted by email. They will have the option to quickly read a summary of the survey topic and delete the survey request if it is not applicable to them. OPMP estimates a burden of 1 minute per non-response, though it is likely to be even lower.

Estimated Number of Responses: It is not possible to precisely predict the number of significant actions or activities that would necessitate OPMP conducting an information collection request. From 2016 to 2019, EPA made approximately 40 requests to OPMP for information across a total of more than 85 crops. From 2020 to 2023, that number of requests was lower, approximately 30 requests. But EPA also issued roughly 200 Proposed Interim Decisions (PIDs) over that time period in addition to more than 100 Draft Risk Assessments (DRAs). OPMP provided written responses to the vast majority of these actions. OPMP does not need to seek additional information for all actions, and each action typically only applies to a subset of crops grown in the United States. However, for actions that apply broadly to multiple crops and regions, OPMP may want to seek broad input from producers of many crops. EPA actions are typically posted to the docket in quarterly batches. Thus, OPMP may be able to combine questions across multiple crops, active ingredients, practices, etc., into one survey. For this collection request, the crop consultant groups (total 14,583) could be contacted up to eight times annually. Up to 15 percent of those may provide responses to questionnaires, or 17,500 responses per year. In addition, other niche groups, up to 1,000 respondents total across groups, may be contacted up to two times annually for an additional 300 responses. This amounts to approximately 17,800 responses per year maximum.

Estimated Number of Responses per Respondent: Respondents will be contacted no more than eight times annually.

Estimated Total Annual Burden on Respondents: 6,131 burden hours annually, or 18,393 hours over the three-year life of the ICR.

Comments are invited on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the

agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to United States Department of Agriculture, 1400 Independence Ave. SW, Room 4054, Washington, DC 20250–9810. All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Cynthia Nickerson,

Deputy Chief Economist, United States Department of Agriculture.

[FR Doc. 2024–02129 Filed 2–1–24; 8:45 am]

BILLING CODE 3410–18–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Supplemental Nutrition Assistance Program Education (SNAP-Ed) Intervention Submission Form and Scoring Tool

AGENCY: Food and Nutrition Service (FNS), Department of Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed revision to the currently approved information collection for the Supplemental Nutrition Assistance Program (SNAP) FNS–885, ''SNAP Education (SNAP-Ed) Intervention Scoring Tool'' and the FNS–886, ''SNAP Education (SNAP-Ed) Intervention Submission Form.'' This revision to forms FNS–885 and FNS–886 will provide an improved user experience by simplifying scoring criteria and clarifying the information requested for certain fields. These updates will also align with the new SNAP-Ed National Program Evaluation and Reporting System (N–PEARS), to ensure consistency with SNAP-Ed specific terms. More information on changes to these forms is in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Comments on this notice must be received on or before April 2, 2024 to be assured of consideration.

ADDRESSES: Comments may be sent to Aurora Calvillo Buffington, Food and Nutrition Service, Supplemental Nutrition Assistance Program, Program Administration and Nutrition Division, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314. Comments may also be submitted via email to *SNAP-Ed@usda.gov* or through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Divyani Pendleton at 703–305–2031 or *Divyani.Pendleton@usda.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of agency functions, 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, including the validity of the methodology and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who respond, including use of appropriate automated, electronic, mechanical, or other technology.

Title: SNAP-Ed Intervention Scoring Tool and SNAP-Ed Intervention Submission Form.

Form Number: FNS–885 and FNS–886.

OMB Number: 0584–0639.

Expiration Date: 9/30/2024.

Type of Request: Revision of a currently approved collection.

Abstract: The Food and Nutrition Act of 2008, as amended (the Act) § 28(c)(3)(A) states that State agencies ''may use funds provided under this section for any evidence-based allowable use of funds'' including ''(i) individual and group-based nutrition education, health promotion, and intervention strategies; (ii) comprehensive, multilevel interventions at multiple complementary organizational and institutional levels; and (iii) community and public health approaches to improve nutrition.'' 7 CFR 272.2(d)(2)(vii)(D) states ''SNAP-Ed activities must include evidence-based activities using two or more of these approaches: individual or group-based nutrition education, health promotion, and intervention strategies; comprehensive, multi-level interventions at multiple complementary organizational and institutional levels; community and public health approaches to improve nutrition and physical activity.''

The *SNAP-Ed Strategies and Interventions: An Obesity Prevention Toolkit for States* (SNAP-Ed Toolkit) was developed collaboratively by FNS National and Regional Office SNAP-Ed staff, the National Collaborative on Childhood Obesity Reduction (NCCOR), and the Association of SNAP Nutrition Education Administrators (ASNNA). Currently, more than 150 interventions are available on the SNAP-Ed Toolkit website *https://snapedtoolkit.org/.* State agencies use the SNAP-Ed Toolkit to locate evidence-based interventions for their implementation of SNAP-Ed programming.

The SNAP-Ed Intervention Submission Form, FNS–886, and the SNAP-Ed Intervention Scoring Tool, FNS–885, provide a uniform and transparent method for submission, review, and scoring of nutrition education, physical activity promotion, and obesity prevention interventions for inclusion in the SNAP-Ed Toolkit. SNAP-Ed State and implementing agencies, nutrition education and public health agencies, and other organizations use these voluntary forms to submit interventions for consideration. The SNAP-Ed Intervention Submission Form and Scoring Tool make it possible for SNAP-Ed implementers and the review committee to determine if the intervention submitted for inclusion in the SNAP-Ed Toolkit is evidence-based and uses one or more of the required approaches. These forms support FNS efforts to increase the selection of interventions available in the SNAP-Ed Toolkit, improve innovation in service delivery using interventions which reflect the latest research, and respond directly to entities submitting interventions (submitters) for the SNAP-Ed Toolkit.

The collection of this information for the submission, review, and scoring of nutrition education, physical activity promotion, and obesity prevention interventions for inclusion in the SNAP-Ed Toolkit is necessary to:

—Provide agencies with an increased selection of interventions to fit their specific needs.
—Increase innovation in service delivery by encouraging adoption of interventions which reflect the latest research on nutrition education, physical activity, and obesity prevention behavior change.
—Allow FNS to respond to each submitter's requests to include their intervention in the SNAP-Ed Toolkit using a clear and transparent review process and inclusion criteria.

Submitters use the FNS–886, SNAP-Ed Intervention Submission Form, to provide information about the intervention they are submitting for inclusion in the SNAP-Ed Toolkit. Information requested includes intervention materials, (such as materials used to develop and test the intervention, evaluation materials, or reports), how these materials have been and will be used, and the evidence base which illustrates their effectiveness. The FNS–886 captures this information through a combination of multiple-choice boxes and text response areas.

Submitters are members of State or implementing agencies, researchers from academic institutions and Federal agencies, and non-profit or private sector nutrition education and physical activity intervention developers.

FNS collects SNAP-Ed Intervention Submission Forms and attachments and distributes them via email to intervention reviewers. Reviewers include relevant FNS staff, relevant staff from other Federal agencies, such as the Centers for Disease Control and Prevention (CDC), researchers from academic institutions, and SNAP-Ed State and implementing agency staff. Reviewers use the Scoring Tool to assess and rate each submission for inclusion in the SNAP-Ed Toolkit. Information from reviewers is collected through a combination of numerical and text entry fields.

FNS will accept interventions to the SNAP-Ed Toolkit in FY 2024. The intervention submission and review period occur biennially.

FNS updated the forms and burden estimates based on consultations with SNAP-Ed State and implementing agency partners, other Federal agencies, and users of the forms. FNS has refined and streamlined the forms where real-world use has indicated this is possible, and included additional instructions, questions, or opportunities for response where users, trainers, and FNS partners indicated areas for improvement. FNS has also made wording changes to fix typographical errors and improve readability. Overall, the changes to the forms are focused on form improvements for the end user.

The following updates to the FNS–886, SNAP-Ed Intervention Submission Form are proposed:

1. Restructuring, formatting, and wording edits to all sections.

2. In Section I, *Intervention Name and Contact Information,* move three questions related to costs and materials to Section VI, *Training, Materials, and Resources.*

3. In Section II, *Intervention Overview,* remove ''Breastfeeding'' and ''Food Insecurity'' and add ''Food Resource Behaviors'' as a Target Behavior category, remove four questions on evaluation and evidence base, and add a question on the core intervention components.

4. In Section III, *Intervention Development,* renumber questions due to the insertion of new questions in Section II.

5. In Section IV, *Evaluation and Outcomes,* add a new question asking submitters to identify tools they used to evaluate their intervention, simplify a question on which outcomes the intervention achieved, and increase the character limit on a question about evidence findings included in the submission. Update section for readability and renumbering to reflect the newly inserted questions.

6. In Section V, *Implementation,* renumber to reflect newly inserted questions.

7. In Section VI, *Training, Materials, and Resources,* clarify training that is required to implement the intervention, and renumber to reflect newly inserted questions.

8. In Section VII, *Intervention Attachments,* add instructions to clarify that submitters should describe how evaluation and modification addressed intervention sustainability concerns, and renumber to reflect newly inserted questions.

9. In Section VIII, *Evaluation Attachments,* add instructions to help submitters name and reference their attachments throughout the submission form.

The following changes to FNS–885, SNAP -Ed Intervention Scoring Tool, are proposed:

1. Rename and restructure all sections to align with the changes to FNS–886, the SNAP-Ed Intervention Submission Form.

2. In Section I, *Intervention Overview and Development,* add three questions on (1) the intervention's ability to address the needs of the target population, (2) the target population and community partner involvement in the intervention development, and (3) SNAP-Ed educators, target population, and/or partner involvement in testing the acceptability of the intervention.

3. In Section II, *Evaluation and Outcomes,* remove ''emerging'' as an evidence base category from the scoring tool, add a question on the use of behavior change theories in the intervention development, and clarify the scoring of intended outcomes and alignment with the SNAP-Ed Evaluation Framework.

4. In Section III, *Implementation,* make minor wording clarifications across questions, and add a question on adaptability of the interventions.

5. In Section IV, *Training, Materials and Resources,* edit questions for clarity and remove one question on interventions adopted by partners in settings not directly supported by SNAP-Ed.

6. In the Bonus Questions, update the list of populations and settings that are currently underrepresented in the SNAP-Ed Toolkit.

Reporting

Affected Public: The affected public for the FNS–886 and FNS–885 forms includes 50 SNAP-Ed State and implementing agencies (37 State/Local/Tribal Governments, 10 non-profit organizations, and 3 for-profit organizations.

Estimated Number of Respondents: The estimated number of respondents is 50. The estimated number of respondents for the Intervention Submission Form is 28 respondents (22 State/Local/Tribal Government, 5 non-profit organizations, and 1 for-profit organization). The estimated number of respondents for the Intervention Scoring Tool is 22 respondents (15 State/Local/Tribal Government, 5 non-profit organizations, and 2 for-profit organizations). This estimate is a decrease based on historical submission data and the expectation that fewer interventions may be submitted to the SNAP-Ed Toolkit on a biennial basis.

Estimated Number of Responses per Respondent: This number of responses per respondent is 1.88 responses, based on the estimate of 94 responses from 50 respondents. FNS expects to receive one response for the Intervention Submission Form, 2 responses for the Intervention Scoring Tool and, 1 required training for the Intervention Scoring Tool. This estimate is unchanged from the previous OMB approval.

Estimated Total Annual Responses: The revised total annual responses is 94, which is a reduction to the current estimated total annual responses of 160

responses. This estimate is a decrease based on historical submission data and expectation that fewer interventions may be submitted to the SNAP-Ed Toolkit on a biennial basis.

Estimated Time per Response: The revised estimated time per response for this voluntary collection is 5.5 hours for the Intervention Submission Form and 3 hours for the Intervention Scoring Tool. This estimate was calculated based on feedback from the stakeholder consultation group. Estimates were averaged based on stakeholder feedback; any data outliers were not included in this estimate. This reflects an increase from the current estimate of 2 hours for the Intervention Submission Form and a decrease from the current estimate of 6 hours for the Intervention Scoring Tool.

Estimated Total Annual Burden on Respondents: The revised estimated total biennial burden on respondents for this voluntary collection receives responses on a biennial basis. The revised estimated total annual burden on respondents for this voluntary collection is 176.5 hours. This revised estimate is a reduction from the current estimated total annual burden of 523 hours. This revised estimate is a decrease based on historical submission data and expectation that fewer interventions may be submitted to the SNAP-Ed Toolkit on a biennial basis.

There are no recordkeeping or third-party/disclosure requirements associated with this information collection.

BURDEN ESTIMATE TABLE

Respondent category	Burden activity	Form	Estimated number of respondents	Responses per respondent	Total annual responses	Estimated hours per response	Estimated total burden hours
State/Local/Tribal Government.	Completing intervention submission form.	FNS–886	22	1	22	5.5	121.0
	Completing intervention scoring tool.	FNS–885	15	2	30	3	90.0
	Training for intervention scoring tool.	FNS–885	15	1	15	1	15.0
Subtotal: State/Local/Tribal Government.	.....		37	.....	67	.....	239.0
Business, Non-Profit	Intervention Submission Form.	FNS–886	5	1	5	5.5	27.5
	Scoring Tool	FNS–885	5	2	10	3	30.0
	Scoring Tool (Training) ...	FNS–885	5	1	5	1	5.0
Subtotal: Business, Non-Profit.	.....		10	.....	20	.....	91.5
Business, Profit	Intervention Submission Form.	FNS–886	1	1	1	5.5	5.5
	Scoring Tool	FNS–885	2	2	4	3	12.0
	Scoring Tool (Training) ...	FNS–885	2	1	2	1	2.0
Subtotal: Business, Profit.	.....		3	.....	7	.....	22.5
Total	.....		50	1.8800	94	3.7553	353.0

Tameka Owens,

Assistant Administrator, Food and Nutrition Service.

[FR Doc. 2024–02064 Filed 2–1–24; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS–2023–0022]

Proposed Revisions to the National Handbook of Conservation Practices for the Natural Resources Conservation Service

AGENCY: Natural Resources Conservation Service, U.S. Department of Agriculture.

ACTION: Notice of availability, request for comments.

SUMMARY: The Natural Resources Conservation Service (NRCS) is giving notice that it intends to issue a series of revised conservation practice standards in the National Handbook of Conservation Practices (NHCP). NRCS is also giving the public an opportunity to provide comments on the specified conservation practice standards in the NHCP.

DATES: We will consider comments that we receive by March 4, 2024.

ADDRESSES: We invite you to submit comments in response to this notice. You may submit your comments through one of the following methods below:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and search for Docket ID NRCS–2023–0022. Follow the online instructions for submitting comments; or
- *Mail or Hand Delivery:* Mr. Bill Reck, National Environmental Engineer, Conservation Engineering Division, NRCS, USDA, 1400 Independence Avenue, South Building, Room 4636, Washington, DC 20250. In your comment, please specify the Docket ID NRCS–2023–0022.

All comments received will be made publicly available on *http://www.regulations.gov.*

The copies of the proposed revised standards are available through *http://www.regulations.gov* by accessing Docket No. NRCS–2023–0022. Alternatively, the proposed revised standards can be downloaded or printed from *https://www.nrcs.usda.gov/getting-assistance/conservation-practices.*

FOR FURTHER INFORMATION CONTACT: Mr. Bill Reck at (202) 317–0245, or email at *bill.reck@usda.gov.* Individuals who require alternative means for communication may contact the USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial

711 for Telecommunications Relay service (both voice and text telephone users can initiate this call from any telephone).

SUPPLEMENTARY INFORMATION:

Background

NRCS plans to revise the conservation practice standards in the NHCP. This notice provides an overview of the planned changes and gives the public an opportunity to offer comments on the specific conservation practice standards and NRCS's proposed changes.

NRCS State Conservationists who choose to adopt these practices in their States will incorporate these practices into the respective electronic Field Office Technical Guide. These practices may be used in conservation systems that treat highly erodible land (HEL) or on land determined to be wetland. Section 343 of the Federal Agriculture Improvement and Reform Act of 1996 (Pub. L. 104–127) requires NRCS to make available for public review and comment all proposed revisions to conservation practice standards used to carry out HEL and wetland provisions of the law.

Revisions to the National Handbook of Conservation Practices

The amount of the proposed changes varies considerably for each of the conservation practice standards addressed in this notice. To fully understand the proposed changes, individuals are encouraged to compare these changes with each standard's current version, which can be found at: *https://www.nrcs.usda.gov/resources/guides-and-instructions/conservation-practice-standards.*

NRCS is requesting comments on the following conservation practice standards:

- Field Border (Code 386);
- Filter Strip (Code 393);
- Grazing Management (Code 528);
- Hedgerow Planting (Code 422);
- Mulching (Code 484);
- Seasonal Water Management for Wildlife (Code 646);
- Structure for Water Control (Code 587); and
- Wetland Restoration (Code 657).

The following are highlights of some of the proposed changes to each standard:

Field Border (Code 386): Revised the ''Purpose'' section to maintain consistency with the current resource concerns. Clarified the wording and formatting to increase readability of the ''General Criteria'' section and added text to the ''Introduction in the Plans and Specifications'' section.

Filter Strip (Code 393): Revised the definition to indicate the location of the filter strip. Revised the ''Purpose'' section to improve clarity and readability, added text to the ''General Criteria'' section to locate the filter strip downslope from a source area of contaminants and added a vegetation section. Added both criteria for flow lengths based on Agronomy Technical Note No. 2, and new content to specify burning frequency. Revised the ''Irrigation Tailwater and Excessive Sediment in Surface Waters'' section to clarify the plant stem spacing.

Grazing Management (Code 528): Changed the title to ''Grazing Management'' to eliminate confusion, promote a sense of adaptability, and better convey the intended purpose. Revised the ''Purpose'' section to add the purpose to reduce plant pest pressure and to create two new purposes from one existing purpose, one addressing soil erosion and the other addressing soil health related resource concerns. Revised the ''General Criteria'' section to include provisions to build resilience and resistance to climate-related disturbances. Added text to clarify that the standard is intended to be used for managing vegetation using herbivores. Added a new statement to the ''Plans and Specifications'' section referring to the National Range and Pasture Manual and clarified that contingency plans need to consider if weather events may be intensified due to climate change. Revised the ''References'' section.

Hedgerow Planting (Code 422): Combined purposes to reduce the numbers from 10 to 5. Pollinator, terrestrial wildlife, and aquatic wildlife purposes were consolidated to a single wildlife purpose. The purposes intercepting airborne particulates, reducing chemical drift and odor movement were combined as a filtering section purpose. Screens and barriers to noise and dust were changed to a barrier section purpose which also includes living fences. Boundary delineation and contour guidelines were removed as a purpose but retained as a consideration.

Mulching (Code 484): Clarified wording and formatting to increase readability. Deleted ''Maintain or increase organic matter content.'' Added ''non-biodegradable'' to synthetic mulches in the ''General Criteria'' section. Revised the ''Moisture Management Additional Criteria'' title to ''Additional Criteria to Improve the Efficiency of Rain-fed Moisture Management, to Improve Irrigation Energy Efficiency, or to Improve the Efficient Use of Irrigation Water.'' Added paragraph on materials to moderate soil temperature to the ''Additional Criteria to Improve Plant Productivity and Health'' section. Added the ''Additional Criteria to Reduce Plant Pest Pressure'' section. Revised the ''Considerations'' section for clarity and formatting to increase readability. Clarified and added an additional purpose in the ''Plans and Specifications'' section. Deleted one purpose on fire damage to mulch material and added a note that some biodegradable mulches can be disked into soil while others should be removed and composted in the ''Operation and Maintenance'' section. Also, added an additional reference to the ''Reference'' section.

Seasonal Water Management for Wildlife (Code 646): Title changed to ''Seasonal Water Management for Wildlife'' to articulate the intent to provide temporary habitat needs through the management of water. Updated the standard to remove development and focus on management. Changed lifespan from 5 years to 1 year to align with other management practices. Development actions will be implemented through implementation of other practices. Added the requirement to use a state approved habitat assessment.

Structure for Water Control (Code 587): Updated formatting of the standard to meet current agency requirements. Minor revisions made for clarity and readability purposes.

Wetland Restoration (Code 657): This standard was last revised in 2010. This practice will have a 15-year span. The primary purpose of this revision was to make plain that this conservation practice standard covers restoration of the abiotic characteristics (hydrology, topography, and soils). Other conservation practice standards are used to restore the plant community. Changes to the ''Purpose'' section were made to adequately align with resource concerns. Made minor changes for clarity and to better describe the practice definition, purpose, criteria, and considerations. Included supporting practices, as well as a list of activities that do not fall under this standard to alleviate confusion. Removed all references to permitting requirements, as those requirements are provided by NRCS national conservation planning policy and should not be included in a technical standard.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, 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, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or 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.

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Louis Aspey,

Associate Chief, Natural Resources Conservation Service.

[FR Doc. 2024–02077 Filed 2–1–24; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

[Docket Number—240126–0025]

Nomination of Individuals to the Federal Economic Statistics Advisory Committee

AGENCY: Bureau of Economic Analysis, Census Bureau, Department of Commerce.

ACTION: Notice of request for nominations.

SUMMARY: The Under Secretary for Economic Affairs requests the nomination of individuals to the Federal Economic Statistics Advisory Committee (FESAC or the Committee). The Under Secretary for Economic Affairs, in coordination with the Directors of the Bureau of Economic Analysis (BEA) and the Census Bureau, as well as the Commissioner of the Department of Labor's Bureau of Labor Statistics (BLS), will consider nominations received in response to this notice, as well as from other sources.

DATES: Nominations for FESAC will be accepted on an ongoing basis and will be considered as and when vacancies arise.

ADDRESSES: Please submit nominations by email to *Gianna.marrone@bea.gov* (subject line ''FESAC Nomination'').

FOR FURTHER INFORMATION CONTACT: Gianna Marrone, Committee Management Official, Department of Commerce, Bureau of Economic Analysis, telephone 301–278–9282, email: *gianna.marrone@bea.gov.*

SUPPLEMENTARY INFORMATION: FESAC was established in accordance with the Federal Advisory Committee Act (5 U.S.C. app. 2). The following sections provide information about the Committee, membership to the Committee, and the Committee's nomination process.

Objectives and Scope of FESAC Activities

The Committee advises the Directors of BEA and the Census Bureau, as well as the Commissioner of BLS, on statistical methodology and other technical matters related to the design, collection, tabulation, and analysis of federal economic statistics.

Description of FESAC Member Duties

The Committee functions solely as an advisory committee to the senior officials of BEA, the Census Bureau, and BLS (the agencies). Important aspects of the Committee's responsibilities include, but are not limited to:

a. Recommending research to address important technical problems arising in the field of federal economic statistics;

b. Identifying areas in which better coordination of the agencies' activities would be beneficial;

c. Exploring ways to enhance the agencies' economic indicators to improve their timeliness, accuracy, and specificity to meet changing demands and future data needs;

d. Improving the means, methods, and techniques to obtain economic information needed to produce current and future economic indicators; and

e. Coordinating, in its identification of agenda items, with other existing academic advisory committees chartered to provide agency-specific advice, for the purpose of avoiding duplication of effort.

The Committee meets once or twice a year, budget permitting. Additional meetings may be held as deemed necessary by the Under Secretary for Economic Affairs or the Designated Federal Official. All Committee meetings are open to the public in accordance with the Federal Advisory Committee Act.

FESAC Membership

The Committee will comprise approximately sixteen members who serve at the pleasure of the Secretary of Commerce. Members shall be appointed by the Under Secretary for Economic Affairs in consultation with the agencies. Committee members shall be professionals in appropriate disciplines, including economists, statisticians, survey methodologists, computer scientists, data scientists, and behavioral scientists who are experts in their fields and are recognized for their scientific, professional, and operational achievements and objectivity. Membership will represent data users with expertise from the public sector, academia, and the private sector. Members will be chosen to achieve a balanced membership that will meet the needs of the agencies.

Members shall serve as Special Government Employees (SGEs) and shall be subject to the applicable ethics rules.

A FESAC member term is three years. Members may serve more than one term as described in the FESAC Charter, available at: *https://apps.bea.gov/fesac/.*

Compensation for Members

Members of the Committee serve without compensation but may be reimbursed for Committee-related travel and lodging expenses.

Solicitation of Nominations

The Committee is currently filling one or more positions on FESAC.

The Under Secretary of Economic Affairs, in consultation with the agencies, will consider nominations of all qualified individuals to ensure that the Committee includes the areas of experience noted above. Individuals may nominate themselves or other individuals. Professional associations and organizations also may nominate one or more qualified persons for Committee membership. Nominations

shall state that the nominee is willing to serve as a Committee member and carry out the affiliated duties. A nomination package should include the following information for each nominee:

1. A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.,* what specific attributes recommend the nominee for service in this capacity), and the nominee's field(s) of expertise;

2. A biographical sketch of the nominee;

3. A copy of the nominee's curriculum vitae; and

4. The name, return address, email address, and daytime telephone number at which the nominator can be contacted.

The Committee aims to have a balanced representation among its members, considering such factors as geography, age, sex, race, ethnicity, technical expertise, community involvement, and knowledge of programs and/or activities related to FESAC. Individuals will be selected based on their expertise in or representation of specific areas as needed by FESAC.

All nomination information should be provided in a single, complete package. Interested applicants should send their nomination packages to Gianna Marrone, Committee Management Official, at *Gianna.Marrone@bea.gov* (subject line ''FESAC Nomination'').

Authority: Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. app.

Dated: January 30, 2024.

Sabrina L. Montes,

Designated Federal Official, Federal Economic Statistics Advisory Committee, Bureau of Economic Analysis.

[FR Doc. 2024–02126 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–848]

Stilbenic Optical Brightening Agents From Taiwan: Preliminary Results of Antidumping Duty Administrative Review; 2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that Teh Fong Min International Co., Ltd., also known as Teh Fong Ming International Co., Ltd. (TFM), the sole producer and/or exporter subject to this administrative review, made sales of stilbenic optical brightening agents (OBAs) at less than normal value during the period of review (POR) May 1, 2022, through November 26, 2022. We invite interested parties to comment on these preliminary results.

DATES: Applicable February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Joshua Weiner, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3902.

SUPPLEMENTARY INFORMATION:

Background

On May 10, 2012, we published in the **Federal Register** the antidumping duty (AD) order on OBAs from Taiwan.[1] On May 2, 2023, we published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order* for the POR.[2] In May 2023, Archroma, U.S., Inc. (Archroma), a U.S. producer of OBAs, timely requested an administrative review of TFM.[3] Additionally, TFM and its affiliated U.S. importer TFM North America, Inc requested a review of TFM.[4] On July 12, 2023, we initiated this administrative review with respect to TFM.[5]

On December 29, 2022, Commerce revoked the *Order* effective November 27, 2022.[6] Because only entries of subject merchandise ''prior to the effective date of revocation will continue to be subject to suspension of liquidation and AD deposit requirements,'' [7] the POR for this administrative review is abbreviated (*i.e.,* May 1, 2022, through November 26, 2022).[8]

For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[9] The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum is available at *https://access.trade.gov/public/FRNoticesListLayout.aspx.* A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Scope of the Order

The products covered by the *Order* are OBAs. A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum.

Preliminary Results of the Administrative Review

As a result of this review, we preliminarily determine that the following estimated weighted-average dumping margin exists for the POR May 1, 2022, through November 26, 2022:

Producer and/or exporter	Weighted-average dumping margin (percent)
Teh Fong Min International Co., Ltd/Teh Fong Ming International Co., Ltd	1.04

Disclosure and Public Comment

We intend to disclose the calculations performed in connection with these preliminary results to interested parties within five days after public announcement of these preliminary results.[10]

[1] *See Certain Stilbenic Optical Brightening Agents from Taiwan: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 77 FR 27419 (May 10, 2012) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 27445, 27447 (May 2, 2023).

[3] *See* Archroma's Letter, ''Request for Administrative,'' dated May 31, 2023.

[4] *See* TFM's Letter, ''Certain Stilbenic Optical Brightening Agents (CSOBA) from Taiwan,'' dated May 30, 2023.

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 44262, 44268 (July 12, 2023).

[6] *See Stilbenic Optical Brightening Agents from People's Republic of China and Taiwan: Final Results of Sunset Reviews and Revocation of Order,* 87 FR 80162 (December 29, 2022) (*Revocation Notice*).

[7] *Id.* 87 FR at 80163.

[8] *Id.*

[9] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review of Certain Stilbenic Optical Brightening Agents from Taiwan; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[10] *See* 19 CFR 351.224(b).

Interested parties may submit case briefs to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of this notice.[11] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[12] Interested parties who submit case or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issues; and (2) a table of authorities.[13]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised in their briefs.[14] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results of this review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain requirements pertaining to the service of documents in 19 CFR 351.303(f).[15]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined.[16] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

[11] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 (for general filing requirements).

[12] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

[14] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[15] *See APO and Service Final Rule.*

[16] *See* 19 CFR 351.310(d).

[17] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[18] *Id.* at 8102–03; *see also* 19 CFR 351.106(c)(2).

[19] *See Order,* 77 FR at 27420.

[20] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[21] *See Revocation Notice,* 87 FR at 80163.

Final Results of Review

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of these preliminary results in the **Federal Register**, unless extended, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

Upon completion of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If the weighted-average dumping margin for TFM is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, we intend to calculate an importer-specific assessment rate based on the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[17] If TFM's weighted-average dumping margin or an importer-specific assessment rate is zero or *de minimis* in the final results of review, we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[18]

For entries of subject merchandise during the POR produced by TFM for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate (*i.e.,* 6.19 percent) [19] if there is no rate for the intermediate company(ies) involved in the transaction.[20]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In the *Revocation Notice,* Commerce stated that it intends to issue instructions to CBP to terminate the suspension of liquidation and to discontinue the collection of cash deposits on entries of subject merchandise, entered or withdrawn from the warehouse, on or after November 27, 2022.[21] Furthermore, because the *Order* has been revoked, Commerce will not issue cash deposit instructions at the conclusion of this administrative review.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.221(b)(4).

Dated: January 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–02138 Filed 2–1–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–985]

Xanthan Gum From the People's Republic of China: Final Results of the Expedited Second 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 xanthan gum from the People's Republic of China (China) would likely lead to continuation or recurrence of dumping at the level indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Luke Caruso, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2081.

SUPPLEMENTARY INFORMATION:

Background

On July 19, 2013, Commerce published the order on xanthan gum from China.[1] On October 2, 2023, Commerce published the notice of initiation of this second sunset review of the *Order,* pursuant to section 751(c)(2) of the Tariff Act of 1930, as amended (the Act).[2]

In October 2023, we received a notice of intent to participate, consistent with 19 CFR 351.218(d), from CP Kelco U.S., Inc. (CP Kelco), a domestic interested party.[3] CP Kelco claimed domestic interested party status under section 771(9)(C) of the Act as a producer of xanthan gum in the United States.[4] Subsequently, on November 1, 2023, CP Kelco submitted a substantive response pursuant to 19 CFR 351.218(d)(3)(i).[5] Commerce received no responses from respondent interested parties with respect to the *Order* covered by this sunset review. Consequently, Commerce notified the U.S. International Trade Commission (ITC),[6] and conducted an expedited (120-day) sunset review of the *Order.*[7]

Scope of the Order

The scope of the *Order* is xanthan gum. For a complete description of the scope of this Order, *see* the Issues and Decision Memorandum.[8]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review are addressed in the accompanying Issues and Decision Memorandum, specifically the likelihood of continuation or recurrence of dumping and the magnitude of the dumping margins likely to prevail if the *Order* were revoked.[9] A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final 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 margin likely to prevail would be up to 154.07 percent.[10]

Notification Regarding Administrative Protective Orders

This notice serves as the only reminder to parties subject to an 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(a)(3). Timely written 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 the final results of this sunset review in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218(e)(1)(ii)(C)(2) and 19 CFR 351.221(c)(5)(ii).

Dated: January 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–02140 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Xanthan Gum from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 78 FR 43143 (July 19, 2013) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 67729 (October 2, 2023).

[3] *See* Domestic Interested Party's Letter, ''Xanthan Gum from the People's Republic of China—Notice of Intent to Participate in Sunset Review,'' dated October 18, 2023 (Notice of Intent to Participate); *see also* Petitioner's Letter, ''Request to File Out of Time due to Extraordinary Circumstances,'' dated October 18, 2023; and Commerce's Letter, ''Acceptance of Notice of Intent to Participate,'' dated October 20, 2023. Because Commerce granted CP Kelco's request for an extension to file its notice of intent to participate, we consider CP Kelco's request to be timely filed pursuant to 19 CFR 351.218(d)(l)(i).

[4] *See* Notice of Intent to Participate at 1.

[5] *See* Domestic Interested Party's Letter, ''*Xanthan Gum from the People's Republic of China: Second Five Year (''Sunset'') Review of Antidumping Duty Order—Domestic Industry Substantive Response,*'' dated November 1, 2023.

[6] *See* Commerce's Letter, ''Sunset Reviews Initiated on October 2, 2023,'' dated October 24, 2023; *see also* 19 CFR 351.218(e)(1)(ii)(C)(1).

[7] *See* 19 CFR 351.218(e)(1)(ii)(C)(2).

[8] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order on Xanthan Gum from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[9] *Id.*

[10] *See Xanthan Gum from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 78 FR 33351, 33353 (June 4, 2013), unchanged in *Order,* 78 FR at 43144.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–874]

Certain Steel Nails From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2021–2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) determines that producers and/or exporters of certain steel nails (steel nails) from the Republic of Korea (Korea) were sold in the United States at less than normal value (NV) during the period of review

(POR) of July 1, 2021, through June 30, 2022.

DATES: Applicable February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Ashley Cossaart or Ajay Menon, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0462 or (202) 482–0208, respectively.

SUPPLEMENTARY INFORMATION:

Background

This review covers 118 producers and/or exporters of the subject merchandise. Commerce selected two mandatory respondents for individual examination: Daejin Steel Company (Daejin) and Korea Wire Co., Ltd. (KOWIRE).[1] The producers/exporters not selected for individual examination are listed in Appendix II.

On July 31, 2023, Commerce published the *Preliminary Results* and invited interested parties to comment.[2] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

Scope of the Order [4]

The merchandise subject to the *Order* is steel nails. For a complete description of the scope of the Order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are listed in Appendix I to this notice and addressed in the Issues and Decision Memorandum. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on the comments received from interested parties, we made certain changes to the margin calculation for Daejin in the *Preliminary Results.* However, these calculation changes did not affect the final weighted-average margin assigned to Daejin. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Determination of No Shipments

As noted in the *Preliminary Results,* we received no shipment claims from Astrotech Steels Private Limited (Astrotech) and Geekay Wires Limited (Geekay) and preliminarily determined that they had no shipments during the POR.[5] We received no comments from interested parties with respect to this preliminary determination of no shipments. Therefore, we continue to find that Astrotech and Geekay had no shipments during the POR.

Final Results of the Review

As a result of this review, we determine the following estimated weighted-average dumping margins for the period February 1, 2021, through January 31, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
Daejin Steel Company	0.66
Korea Wire Co., Ltd	0.00
Companies Not Selected for Individual Review [6]	0.66

Disclosure

Commerce intends to disclose the calculations performed for Daejin in connection with these final results to interested parties within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Pursuant to 19 CFR 351.212(b)(1), because Daejin and KOWIRE reported the entered value for all of their U.S. sales, we calculated importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's ''automatic assessment'' practice will apply to entries of subject merchandise during the POR produced by Daejin or KOWIRE for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[7]

For the companies that were not selected for individual review, we assigned an assessment rate based on the review-specific average rate, calculated as noted in the ''Final Results of the Review'' section, above. Further, because we continue to find that Astrotech and Geekay had no shipments of subject merchandise during the POR, we will instruct CBP to liquidate any suspended entries that entered under these companies' antidumping duty case numbers at the all-others rate. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[8]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the

[1] *See* Memorandum, ''Respondent Selection,'' dated October 11, 2022.

[2] *See Certain Steel Nails from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Determination of No Shipments, and Partial Rescission of Antidumping Duty Administrative Review; 2021–2022,* 88 FR 49443 (July 31, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[3] *See* Memorandum, ''Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Steel Nails from the Republic of Korea; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[4] *See Certain Steel Nails from the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 80 FR 39994 (July 13, 2015) (*Order*).

[5] *See Preliminary Results.*

[6] The exporters and/or producers not selected for individual review are listed in Appendix II. For a discussion of the methodology used to calculate the rate for non-selected respondents, *see Preliminary Results,* 88 FR at 49444.

[7] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[8] *See* section 751(a)(2)(C) of the Act.

time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rates for the reviewed companies will be the rates shown above, except if the rate is less than 0.50 percent (*de minimis* within the meaning of 19 CFR 351.106(c)(1)), the cash deposit will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a previous review, or the less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all-other manufacturers or exporters will continue to be 11.80 percent, the all-others rate established in the LTFV investigation.[9] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (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 this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(5).

Dated: January 26, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

Appendix II

Review-Specific Average Rate Applicable to Companies Not Selected for Individual Review

1. Agl Co., Ltd.
2. Americana Express (Shandong) Co. Ltd.
3. Ansing Fasteners Co. Ltd.
4. Beijing Catic Industry Limited
5. Beijing Jinheung Co., Ltd.
6. Big Mind Group Co., Ltd.
7. Changzhou Kya Trading Co., Ltd.
8. China Staple Enterprise Tianjin Co. Ltd.
9. D&F Material Products Ltd.
10. De Well Group Korea Co., Ltd.
11. Dezhou Hualude Hardware Products Co. Ltd.
12. DLF Industry Co., Limited
13. Doublemoon Hardware Company Ltd.
14. DT China (Shanghai) Ltd.
15. Duo-Fast Korea Co. Ltd.
16. Ejen Brothers Limited
17. England Rich Group (China) Ltd.
18. Ever Leading International Inc.
19. Fastgrow International Co., Inc.
20. Glovis America, Inc.
21. GWP Industries (Tianjin) Co., Ltd.
22. Haas Automation Inc.
23. Han Express Co. Ltd.
24. Handuk Industrial Co., Ltd.
25. Hanmi Staple Co., Ltd.
26. Hebei Minmetals Co., Ltd.
27. Hebei Longshengyuan Trade Co Ltd.
28. Hebei Cangzhou New Century Foreign Trade Co., Ltd.
29. Hebei Shinyee Trade Co., Ltd.
30. Hengtuo Metal Products Company Limited
31. Home Value Co., Ltd.
32. Hongyi (Hk) Hardware Products Co., Limited
33. Hongyi (Hk) Industrial Co., Limited
34. Huanghua RC Business Co., Ltd.
35. Huanghua Yingjin Hardware Products Co., Ltd.
36. Inmax Industries Sdn. Bhd.
37. JCD Group Co., Limited
38. Je-il Wire Production Co., Ltd.
39. Jinheung Steel Corporation
40. Jining Jufu International Trade Co.
41. Jinsco International Corporation
42. Joo Sung Sea & Air Co., Ltd.
43. Jushiqiangsen (Tianjin) International Trade Co., Ltd.
44. Kabool Fasteners Co. Ltd.
45. KB Steel
46. Kerry-Apex (Thailand) Co., Ltd.
47. Koram Inc.
48. KPF Co., Ltd.
49. Kuehne & Nagel Ltd.
50. Linyi Double-Moon Hardware Products Co., Ltd.
51. Linyi Flyingarrow Imp. & Exp. Co., Ltd.
52. Linyi Jianchengde Metal Hardware Co.
53. Linyi Yitong Chain Co., Ltd.
54. Manho Rope and Wire Ltd.
55. Max Co., Ltd.
56. Mingguang Ruifeng Hardware Products Co., Ltd.
57. Nanjing Senqiao Trading Co., Ltd.
58. Needslink, Inc.
59. Ocean King International Industries Limited
60. Paslode Fasteners (Shanghai) Co., Ltd.
61. Peace Korea Co., Ltd.
62. Qingdao Ant Hardware Manufacturing Co., Ltd.
63. Qingdao Best World Industry-Trading Co., Ltd.
64. Qingdao Cheshire Trading Co., Ltd.
65. Qingdao Hongyuan Nail Industry Co., Ltd.
66. Qingdao Jcd Machinery Co., Ltd.
67. Qingdao Jiawei Industry Co., Limited
68. Qingdao Jisco Co., Ltd.
69. Qingdao Master Metal Products Co., Ltd.
70. Qingdao Meijialucky Industry and Co.
71. Qingdao Mst Industry And Commerce Co., Ltd.
72. Qingdao Ruitai Trade Co., Ltd.
73. Qingdao Shantron Int'l Trade Co., Ltd.
74. Qingdao Shenghengtong Metal Products Co., Ltd.
75. Qingdao Sunrise Metal Products Co., Ltd.
76. Qingdao Tian Heng Xiang Metal Products Co., Ltd.

[9] *See Order,* 80 FR at 39996.

77. Qingdao Top Metal Industrial Co., Ltd.
78. Rewon Systems, Inc.
79. Rise Time Industrial Ltd.
80. Shandong Dominant Source Group Co., Ltd.
81. Shandong Guomei Industry Co., Ltd.
82. Shanghai Curvet Hardware Products Co., Ltd.
83. Shanghai Goldenbridge International Co., Ltd.
84. Shanghai Pinnacle International Trading Co., Ltd.
85. Shanghai Zoonlion Industrial Co., Ltd.
86. Shanxi Pioneer Hardware Industrial Co., Ltd.
87. Shanxi Sanhesheng Trade Co., Ltd.
88. Shaoxing Bohui Import & Export Co., Ltd.
89. Shijiazhuang Yajiada Metal Products Co., Ltd.
90. Shijiazhuang Tops Hardware Manufacturing Co., Ltd.
91. Shin Jung TMS Corporation Ltd.
92. SSS Hardware International Trading Co., Ltd.
93. Storeit Services LLP
94. Test Rite International Co., Ltd.
95. Tangshan Jason Metal Materials Co., Ltd.
96. The Inno Steel Industry Company
97. Tianjin Bluekin Industries Limited.
98. Tianjin Coways Metal Products Co., Ltd.
99. Tianjin Hweschun Fasteners Manufacturing Co. Ltd.
100. Tianjin Jinchi Metal Products Co., Ltd.
101. Tianjin Jinghai County Hongli Industry and Business Co., Ltd.
102. Tianjin Jinzhuang New Material Sci Co., Ltd.
103. Tianjin Lianda Group Co., Ltd.
104. Tianjin Zhonglian Metals Ware Co., Ltd.
105. Tianjin Zhonglian Times Technology Co., Ltd.
106. Un Global Company Limited
107. Unicorn (Tianjin) Fasteners Co., Ltd.
108. United Company For Metal Products
109. W&K Corporation Limited
110. Weifang Wenhe Pneumatic Tools Co., Ltd.
111. Wulian Zhanpengmetals Co., Ltd.
112. WWL India Private Ltd.
113. Xian Metals And Minerals Import And Export Co., Ltd.
114. Youngwoo Fasteners Co., Ltd.
115. Zhangjiagang Lianfeng Metals Products Co., Ltd.
116. Zhaoqing Harvest Nails Co., Ltd.

[FR Doc. 2024–02112 Filed 2–1–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review and Join Annual Inquiry Service List

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

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the U.S. Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to release the CBP data under administrative protective order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review, or changed circumstances review). For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to: (a) identify which companies subject to review previously were collapsed; and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity to Request a Review: Not later than the last day of February 2024,[2] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in February for the following periods:

	Period
Antidumping Duty Proceedings	
ARGENTINA: Prestressed Concrete Steel Wire Strand, A–357–822	2/1/23–1/31/24
BRAZIL: Lemon Juice from Brazil, A–351–858	8/4/22–1/31/24
COLOMBIA: Prestressed Concrete Steel Wire Strand, A–301–804	2/1/23–1/31/24
EGYPT: Prestressed Concrete Steel Wire Strand, A–729–804	2/1/23–1/31/24
INDIA:	
Certain Cut-To-Length Carbon-Quality Steel Plate, A–533–817	2/1/23–1/31/24
Certain Preserved Mushrooms, A–533–813	2/1/23–1/31/24
Certain Frozen Warmwater Shrimp, A–533–840	2/1/23–1/31/24
Sodium Nitrite, A–533–906	8/17/22–1/31/24
Stainless Steel Bar, A–533–810	2/1/23–1/31/24
INDONESIA:	
Certain Cut-To-Length Carbon-Quality Steel Plate, A–560–805	2/1/23–1/31/24
Certain Preserved Mushrooms, A–560–802	2/1/23–1/31/24
ITALY: Stainless Steel Butt-Weld Pipe Fittings, A–475–828	2/1/23–1/31/24
JAPAN: Carbon Steel Butt-Weld Pipe Fittings, A–588–602	2/1/23–1/31/24
MALAYSIA: Stainless Steel Butt-Weld Pipe Fittings, A–557–809	2/1/23–1/31/24
MEXICO: Large Residential Washers, A–201–842	2/1/23–1/31/24
PHILIPPINES: Stainless Steel Butt-Weld Pipe Fittings, A–565–801	2/1/23–1/31/24
REPUBLIC OF KOREA: Certain Cut-To-Length Carbon-Quality Steel Plate, A–580–836	2/1/23–1/31/24
SAUDI ARABIA: Prestressed Concrete Steel Wire Strand, A–517–806	2/1/23–1/31/24
SOCIALIST REPUBLIC OF VIETNAM:	
Certain Frozen Warmwater Shrimp, A–552–802	2/1/23–1/31/24
Steel Wire Garment Hangers, A–552–812	2/1/23–1/31/24
Utility Scale Wind Towers, A–552–814	2/1/23–1/31/24
SOUTH AFRICA:	
Carbon and Alloy Steel Cut-To-Length Plate, A–791–822	2/1/23–1/31/24
Lemon Juice, A–791–827	8/4/22–1/31/24
TAIWAN:	
Carbon and Alloy Steel Threaded Rod, A–583–865	2/1/23–1/31/24
Crystalline Silicon Photovoltaic Products, A–583–853	2/1/23–1/31/24
Prestressed Concrete Steel Wire Strand, A–583–868	2/1/23–1/31/24
THAILAND: Certain Frozen Warmwater Shrimp, A–549–822	2/1/23–1/31/24
THE NETHERLANDS: Prestressed Concrete Steel Wire Strand, A–421–814	2/1/23–1/31/24
THE PEOPLE'S REPUBLIC OF CHINA:	
Certain Preserved Mushrooms, A–570–851	2/1/23–1/31/24
Common Alloy Aluminum Sheet, A–570–073	2/1/23–1/31/24
Crystalline Silicon Photovoltaic Products, A–570–010	2/1/23–1/31/24
Certain Frozen Warmwater Shrimp, A–570–893	2/1/23–1/31/2
Heavy Forged Hand Tools, With or Without Handles, A–570–803	2/1/23–1/31/24
Large Residential Washers, A–570–033	2/1/23–1/31/24
Rubber Bands, A–570–069	2/1/23–1/31/24
Small Diameter Graphite Electrodes, A–570–929	2/1/23–1/31/24
Truck and Bus Tires, A–570–040	2/1/23–1/31/24
Uncovered Innerspring Units, A–570–928	2/1/23–1/31/24
Utility Scale Wind Towers, A–570–981	2/1/23–1/31/24
Wood Mouldings and Millwork Products, A–570–117	2/1/23–1/31/24
TURKEY:	
Certain Carbon and Alloy Steel Cut-To-Length Plate, A–489–828	2/1/23–1/31/24
Prestressed Concrete Steel Wire Strand, A–489–842	2/1/23–1/31/24
UNITED ARAB EMIRATES: Prestressed Concrete Steel Wire Strand, A–520–809	2/1/23–1/31/24
Countervailing Duty Proceedings	
INDIA:	
Certain Cut-To-Length Carbon-Quality Steel Plate, C–533–818	1/1/23–12/31/23

[2] Or the next business day, if the deadline falls on a weekend, federal holiday, or any other day when Commerce is closed. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

	Period
Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, C–533–874	1/1/23–12/31/23
Prestressed Concrete Steel Wire Strand, C–533–829	1/1/23–12/31/23
Sodium Nitrite, C–533–907	6/21/22–12/31/23
INDONESIA: Certain Cut-To-Length Carbon-Quality Steel Plate, C–560–806	1/1/23–12/31/23
REPUBLIC OF KOREA: Certain Cut-To-Length Carbon-Quality Steel Plate, C–580–837	1/1/23–12/31/23
SOCIALIST REPUBLIC OF VIETNAM: Steel Wire Garment Hangers, C–552–813	1/1/23–12/31/23
THE PEOPLE'S REPUBLIC OF CHINA:	
Cold-Drawn Mechanical Tubing, C–570–059	1/1/23–12/31/23
Common Alloy Aluminum Sheet, C–570–074	1/1/23–12/31/23
Crystalline Silicon Photovoltaic Products, C–570–011	1/1/23–12/31/23
Rubber Bands, C–570–070	1/1/23–12/31/23
Truck and Bus Tires, C–570–041	1/1/23–12/31/23
Utility Scale Wind Towers, C–570–982	1/1/23–12/31/23
Wood Mouldings and Millwork Products, C–570–118	1/1/23–12/31/23
TURKEY: Prestressed Concrete Steel Wire Strand, C–489–843	1/1/23–12/31/23

Suspension Agreements

None.

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[3]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.[4] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[5] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *https://access.trade.gov*.[6] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[7]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of February 2024. If Commerce does not receive, by the last day of February 2024, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated

[3] *See* the Enforcement and Compliance website at *https://www.trade.gov/us-antidumping-and-countervailing-duties.*

[4] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[5] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[6] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[7] *See Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule,* 88 FR 67069 (September 29, 2023).

antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

Establishment of and Updates to the Annual Inquiry Service List

On September 20, 2021, Commerce published the final rule titled ''*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*'' in the **Federal Register**.[8] On September 27, 2021, Commerce also published the notice entitled ''*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*'' in the **Federal Register**.[9] The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.[10]

In accordance with the *Procedural Guidance,* for orders published in the **Federal Register** before November 4, 2021, Commerce created an annual inquiry service list segment for each order and suspended investigation. Interested parties who wished to be added to the annual inquiry service list for an order submitted an entry of appearance to the annual inquiry service list segment for the order in ACCESS, and on November 4, 2021, Commerce finalized the initial annual inquiry service lists for each order and suspended investigation. Each annual inquiry service list has been saved as a public service list in ACCESS, under each case number, and under a specific segment type called ''AISL-Annual Inquiry Service List.'' [11]

As mentioned in the *Procedural Guidance,* beginning in January 2022, Commerce will update these annual inquiry service lists on an annual basis when the *Opportunity Notice* for the anniversary month of the order or suspended investigation is published in the **Federal Register**.[12] Accordingly, Commerce will update the annual inquiry service lists for the above-listed antidumping and countervailing duty proceedings. All interested parties wishing to appear on the updated annual inquiry service list must take one of the two following actions: (1) new interested parties who did not previously submit an entry of appearance must submit a new entry of appearance at this time; or (2) interested parties who were included in the preceding annual inquiry service list must submit an amended entry of appearance to be included in the next year's annual inquiry service list. For these interested parties, Commerce will change the entry of appearance status from ''Active'' to ''Needs Amendment'' for the annual inquiry service lists corresponding to the above-listed proceedings. This will allow those interested parties to make any necessary amendments and resubmit their entries of appearance. If no amendments need to be made, the interested party should indicate in the area on the ACCESS form requesting an explanation for the amendment that it is resubmitting its entry of appearance for inclusion in the annual inquiry service list for the following year. As mentioned in the *Final Rule,*[13] once the petitioners and foreign governments have submitted an entry of appearance for the first time, they will automatically be added to the updated annual inquiry service list each year.

Interested parties have 30 days after the date of this notice to submit new or amended entries of appearance. Commerce will then finalize the annual inquiry service lists five business days thereafter. For ease of administration, please note that Commerce requests that law firms with more than one attorney representing interested parties in a proceeding designate a lead attorney to be included on the annual inquiry service list.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at *https://access.trade.gov*.

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule,* Commerce stated that, ''after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.'' [14] Accordingly, as stated above and pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

This notice is not required by statute but is published as a service to the international trading community.

Dated: January 29, 2024.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2024–02113 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021) (*Final Rule*).

[9] *See Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions,* 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

[10] *Id.*

[11] This segment has been combined with the ACCESS Segment Specific Information (SSI) field which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A–000–000 that was published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as ''AISL-January Anniversary.'' Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

[12] *See Procedural Guidance,* 86 FR 53206.

[13] *See Final Rule,* 86 FR 52335.

[14] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–071]

Sodium Gluconate, Gluconic Acid, and Derivative Products From the People's Republic of China: Final Results of 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 sodium gluconate, gluconic acid, and derivative products (sodium gluconate) from the People's Republic of China (China) would likely lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Stephanie Trejo, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4390.

SUPPLEMENTARY INFORMATION:

Background

On November 13, 2018, Commerce published the AD order on sodium gluconate from China.[1] On October 2, 2023, Commerce initiated the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act),[2] and subsequently, a domestic interested party [3] timely submitted its complete notice of intent to participate [4] and adequate substantive response regarding this review.[5] The domestic interested party claimed interested party status under section 771(9)(C) of the Act as a producer of the domestic like product in the United States.[6] Commerce did not receive a substantive response from any respondent interested party, nor was a hearing requested. On November 17, 2023, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive adequate substantive responses from respondent interested parties.[7] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the *Order*.

[1] *See Sodium Gluconate, Gluconic Acid and Derivative Products from the People's Republic of China: Antidumping and Countervailing Duty Orders,* 83 FR 56299 (November 13, 2018) *(Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 67729 (October 2, 2023).

[3] The domestic interested party is PMP Fermentation Products, Inc.

[4] *See* Domestic Interested Party's Letter, ''Sodium Gluconate, Gluconic Acid and Derivative Products from the People's Republic of China—Domestic Interested Parties' Notice of Intent to Participate,'' dated October 12, 2023.

[5] *See* Domestic Interested Party's Letter, ''Sodium Gluconate, Gluconic Acid and Derivative Products from the People's Republic of China''—Domestic Interested Parties' Substantive Response,'' dated November 1, 2023.

[6] *Id.*

[7] *See* Commerce's Letter ''Sunset Reviews Initiated on October 2, 2023,'' dated November 17, 2023.

Scope of the Order

The product covered by the *Order* is sodium gluconate from China. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[8]

Analysis of Comments Received

A complete discussion of all issues raised in this review, including the likelihood of continuation or recurrence of dumping and the magnitude of the dumping margins likely to prevail if the *Order* were revoked, is provided in the Issues and Decision Memorandum.[9] A list of the topics in the Issues and Decision Memorandum is 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 accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

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 likely lead to continuation or recurrence of dumping, and that the magnitude of the dumping margin likely to prevail would be up to 213.15 percent.[10]

Administrative Protective Order

This notice serves as the only reminder to interested parties subject to an administrative protective order (APO) of their responsibility concerning the return/destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results of sunset reviews in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act, and 19 CFR 351.218(e)(1)(ii)(C)(2) and 19 CFR 351.221(c)(5)(ii).

Dated: January 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Sections in the Issues and Decision Memorandum

[FR Doc. 2024–02117 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Antidumping Duty Order on Sodium Gluconate, Gluconic Acid, and Derivative Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[9] *Id.*

[10] *Id.* at 9.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–820]

Prestressed Concrete Steel Wire Strand From Thailand: Preliminary Results of Antidumping Duty Administrative Review; 2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that prestressed concrete steel wire strand (PC strand) from Thailand was not sold in the United States at less than normal value (NV) during the period of review (POR) January 1, 2022, through December 31, 2022. We invite interested parties to comment on these preliminary results of review.

DATES: Applicable February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Samantha Kinney, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2285.

SUPPLEMENTARY INFORMATION:

Background

On January 28, 2004, Commerce published in the **Federal Register** the antidumping (AD) duty order on PC strand from Thailand.[1] On January 3,

[1] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping*

2023, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order* for the POR.[2] On March 14, 2023, based on timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an AD administrative review of the *Order,* covering one producer/exporter, The Siam Industrial Wire Co., Ltd. (SIW).[3]

Pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), on September 12, 2023, Commerce extended the deadline for the preliminary results of this review until January 31, 2024.[4] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5]

Scope of the Order

The merchandise covered by the *Order* is PC strand from Thailand. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a) of the Act. Constructed export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is available 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 Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of Review

We preliminarily determine the following weighted-average dumping margin exists for the period January 1, 2022, through December 31, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
The Siam Industrial Wire Co., Ltd	0.00

Disclosure and Public Comment

Commerce intends to disclose the calculations performed for these preliminary results to interested parties within five days after public announcement, or if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**.[6] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[7] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[8] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[9]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[10] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[11]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. If a request for a hearing is made, Commerce intends to hold a hearing at a time and date to be determined.[12] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

All submissions, including case and rebuttal briefs, as well as hearing requests, should be filed using ACCESS.[13] An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act, upon completion of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, ADs on all appropriate entries of subject merchandise covered by this review.[15] If the weighted-average dumping margin for SIW is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, and because SIW reported entered values for all of its sales, Commerce intends to calculate importer-specific *ad valorem* assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales, in accordance with 19 CFR 351.212(b)(1).

Duty Order: Prestressed Concrete Steel Wire Strand from Thailand, 69 FR 4111 (January 28, 2004) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 45 (January 3, 2023).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 15642 (May 14, 2023).

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated September 12, 2023.

[5] *See* Memorandum, ''Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Prestressed Concrete Steel Wire Strand from Thailand; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* 19 CFR 351.224(b).

[7] *See* 19 CFR 351.303 (for general filing requirements).

[8] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Final Service Rule*).

[9] *See* 19 CFR 351.309(c)(2) and (d)(2).

[10] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[11] *See APO and Final Service Rule.*

[12] *See* 19 CFR 351.310(d).

[13] *See* 19 CFR 351.303.

[14] *See APO and Final Service Rule.*

[15] *See* 19 CFR 351.212(b).

We intend to instruct CBP to assess ADs on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* 0.50 percent). If SIW's overall weighted-average dumping margin is zero or *de minimis* or where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of review, we intend to instruct CBP to liquidate the appropriate entries without regard to ADs.[16] The final results of this administrative review shall be the basis for the assessment of ADs on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[17]

For entries of subject merchandise during the POR produced by SIW for which it did not know that the merchandise was destined for the United States, we intend to instruct CBP to liquidate unreviewed entries at the all-others rate (*i.e.,* 12.91 percent) in the original less-than-fair-value (LTFV) investigation [18] if there is no rate for the intermediate company(ies) involved in the transaction.[19]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication in the **Federal Register** of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for SIW will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for merchandise exported by a company not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific cash deposit rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review, or a previous segment, but the producer is, then the cash deposit rate will be the rate established in the completed segment for the most recent period for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 12.91 percent, the all-others rate established in the LTFV investigation.[20] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless the deadline is otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised by interested parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**.[21]

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of ADs prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of ADs occurred and the subsequent assessment of doubled ADs.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 19 CFR 351.221(b)(4).

Dated: January 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–02142 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–DS–P

[16] *See* 19 CFR 351.106(c)(2); *see also Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[17] *See* section 751(a)(2)(C) of the Act.

[18] *See Order,* 69 FR at 4111.

[19] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[20] *See Order,* 69 FR at 4111.

[21] *See* section 751(a)(3)(A) of the Act; *see also* 19 CFR 351.213(h).

DEPARTMENT OF COMMERCE

International Trade Administration

[Docket Number: 231208–0290]

RIN 0625–XZ100

Announcing an Importer's Additional Declaration in the Automated Commercial Environment Specific to Antidumping/Countervailing Duty Certifications

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

ACTION: General notice.

SUMMARY: The U.S. Department of Commerce (Commerce), in coordination with U.S. Customs and Border Protection (CBP), is announcing a new functionality in the Automated Commercial Environment (ACE) for importers entering merchandise that is the subject of an antidumping and/or countervailing duty (AD/CVD) certification. Specifically, the capability will exist for importers to identify in the ACE entries that are the subject of an AD/CVD certification. Commerce intends to instruct parties to use this new functionality on a case-by-case basis. This new identification mechanism will facilitate Commerce's and CBP's administration of the AD/CVD laws by making such entry summaries more readily identifiable to Commerce and CBP.

DATES: This new functionality will be effective May 2, 2024.

FOR FURTHER INFORMATION CONTACT: For technical questions related to ACE, contact your assigned CBP client representative. Interested parties without an assigned CBP client representative should direct their questions to: *gmb.clientrepoutreach@cbp.dhs.gov.* For general questions related to the new declaration capability, contact Michael Walsh or Yasmin Bordas, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; email: *Michael.Walsh@trade.gov* or *Yasmin.Bordas@trade.gov,* respectively.

SUPPLEMENTARY INFORMATION: This notice announces functionality in ACE for an Importer's Additional Declaration

specific AD/CVD certifications. For years, Commerce has used certification requirements as a way for parties to support claims concerning the applicability of an AD/CVD order to merchandise that they are producing, exporting and/or importing.[1] More recently, on September 20, 2021, Commerce published amendments to its existing regulations at 19 CFR part 351 to strengthen and improve the administration and enforcement of the AD/CVD laws.[2] Included in this final rule is the new regulation at 19 CFR 351.228, which became applicable on October 20, 2021, that codifies and enhances Commerce's existing authority and practice to require certifications by importers and other interested parties as to whether merchandise is subject to an AD/CVD order. Pursuant to 19 CFR 351.228(a)(1)(i)–(iii), the Secretary of Commerce may determine in the context of an AD/CVD proceeding that an importer or other interested party shall ''maintain a certification for entries of merchandise into the customs territory of the United States,'' ''provide a certification by electronic means at the time of entry or entry summary,'' or ''otherwise demonstrate compliance with a certification requirement as determined by the Secretary, in consultation with the Customs Service.''

Since the time we published this regulation, there is a new reporting functionality in ACE that will allow the importer to enter a specific importer's additional declaration type code, which will be transmitted through the Automated Broker Interface, and indicate that merchandise is being entered into the customs territory of the United States subject to an accompanying AD/CVD certification. ACE will then reflect the indication under the new Importer's Additional Declaration. In light of this new functionality, when the Secretary determines in the context of an AD/CVD proceeding that a certification is required, the Secretary may determine, alone or in conjunction with other requirements, that the importer shall declare that its merchandise is being entered subject to a certification requirement using an additional declaration type code in ACE at the time of entry summary. This code will represent a claim that, for example, the entered merchandise is entitled to a specific company AD and/or CVD rate or, alternatively, a claim that the entered merchandise is not subject to AD and/or CVD order. Use of this increased visibility in ACE will strengthen Commerce's and CBP's enforcement of AD/CVD orders, enabling them to more easily identify merchandise that is being entered subject to an AD/CVD certification. Accordingly, as of the effective date identified above and as determined by the Secretary in a given AD/CVD proceeding, Commerce and CBP may require that importers entering merchandise into customs territory of the United States that is the subject of an AD/CVD certification identify their merchandise as such with the new importer's additional declaration type code submitted at the time of entry summary. The Cargo Systems Messaging Service (CSMS) message announcing this new functionality will provide additional instructions regarding the importer's additional declaration type code.

Dated: January 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–02114 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See, e.g., Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination and Affirmative Preliminary Determination of Critical Circumstances, in Part,* 77 FR 31309, 31323–24 (May 25, 2012), unchanged in *Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, and Affirmative Final Determination of Critical Circumstances, in Part,* 77 FR 63791 (October 17, 2012), and accompanying Issues and Decision Memorandum at note 33; *Certain Cold-Rolled Steel Flat Products from the People's Republic of China: Affirmative Final Determination of Circumvention of the Antidumping Duty and Countervailing Duty Orders,* 83 FR 23891, 23892 (May 23, 2018), and accompanying Issues and Decision Memorandum at Comment 4.

[2] *See Regulations To Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws,* 86 FR 52300 (September 20, 2021).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–894]

Forged Steel Fluid End Blocks From India: Preliminary Results of Countervailing Duty Administrative Review and Rescission of Administrative Review, in Part; 2022

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies were provided to Bharat Forge Limited, the sole producer and exporter of forged steel fluid end blocks (fluid end blocks) from India subject to this administrative review, during the period of review (POR) January 1, 2022, through December 31, 2022. We invite interested parties to comment on these preliminary results.

DATES: Applicable February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Suresh Maniam, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1603.

SUPPLEMENTARY INFORMATION:

Background

On January 29, 2021, Commerce published in the **Federal Register** the countervailing duty order on fluid end blocks from India.[1] On January 3, 2023, we published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order*.[2] On March 14, 2023, based on timely requests for an administrative review, Commerce published in the **Federal Register** the notice of initiation of an administrative review of the *Order*.[3] On May 5, 2023, Commerce selected Bharat Forge, Limited as the sole mandatory respondent in this review.[4] On September 19, 2023, Commerce extended the deadline for the preliminary results of this review until January 31, 2024.[5]

For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.[6] A list of topics discussed in the Preliminary Decision Memorandum is included in the appendix to this notice. The Preliminary 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

[1] *See Forged Steel Fluid End Blocks from India: Countervailing Duty Order,* 86 FR 7535 (January 29, 2021) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 88 FR 45 (January 3, 2023).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 15642 (March 14, 2023).

[4] *See* Memorandum, ''Respondent Selection Memorandum,'' dated May 5, 2023.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results,'' dated September 19, 2023.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Countervailing Duty Administrative Review and Rescission of Review in Part: Forged Steel Fluid End Blocks from India; 2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The product covered by the *Order* is fluid end blocks from India. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this countervailing duty administrative review in accordance with section 751(a)(1) of the Tariff Act of 1930, as amended (the Act). For each subsidy program found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying our conclusions, including our reliance, in part, on facts otherwise available pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Based on our analysis of U.S. Customs and Border Protection (CBP) data, we determine that the following companies had no entries of subject merchandise during the POR: (1) Bharat Forge Limited, India; (2) Echjay Industries Pvt. Ltd.; (3) Jaypee Forge Pvt. Ltd.; (4) MM Forgings Ltd. (a.k.a., M M Forgings Ltd.); (5) Mars Forge Pvt. Ltd.; (6) Pradeep Metals Ltd.; (7) Ramkrishna Forgings Ltd.; (8) Rolex Rings Ltd.; (9) Sunrise Exports International; (10) Western Heat and Forge Pvt. Ltd.; and (11) Western India Forgings Pvt. Ltd. On June 29, 2023, we notified parties of our intent to rescind the administrative review with respect to these 11 companies because there are no reviewable suspended entries.[8] No parties commented on the notification of intent to rescind the review, in part. Pursuant to 19 CFR 351.213(d)(3), we are rescinding the administrative review of these 11 companies. For additional information regarding this determination, see the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminary find that the net countervailable subsidy rate exists for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent *ad valorem*)
Bharat Forge Limited[9]	3.76

Disclosure and Public Comment

We intend to disclose the calculations performed for these preliminary results to interested parties within five days after the date of publication of this notice.[10] Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of these preliminary results of review.[13] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[11] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[12]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[13] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. eastern time within 30 days after the date of publication of this notice.

Unless extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment Rates

In accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.221(b)(4)(i), we preliminarily determined subsidy rates in the amounts shown above for the producer/exporters shown above. Upon issuance of the final results of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review.

For the companies for which this review is rescinded with these preliminary results, we will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2022, through December 31, 2022, in accordance with 19 CFR 351.212(c)(l)(i). For the companies remaining in the review, we intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**.

If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] *See* Memorandum, ''Intent to Rescind Review, in Part,'' dated June 29, 2023 (Intent to Rescind Memo).

[9] Commerce preliminarily finds the following companies to be cross-owned with Bharat Forge, Limited: Bharat Forge Utilities Limited and Saarloha Advanced Materials Private Limited.

[10] See 19 CFR 351.224(b).

[11] See 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (APO and Final Service Rule).

[12] See 19 351.309(c)(2) and (d)(2).

[13] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[14] *See APO and Final Service Rule.*

statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce also intends upon publication of the final results, to instruct CBP to collect cash deposits of the estimated countervailing duties in the amounts calculated in the final results of this review for the respective companies listed above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. If the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required on shipments of the subject merchandise entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213 and 351.221(b)(4).

Dated: January 26, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–02139 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–072]

Sodium Gluconate, Gluconic Acid, and Derivative Products From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

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

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on sodium gluconate, gluconic acid, and derivative products (sodium gluconate) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Stephanie Trejo, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4390.

SUPPLEMENTARY INFORMATION:

Background

On November 13, 2018, Commerce published the CVD order on sodium gluconate from China.[1] On October 2, 2023, Commerce published the notice of initiation of the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On October 12, 2023, Commerce received a timely notice of intent to participate from PMP Fermentation Products Inc. (the domestic interested party) within the 15-day deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v) as producers of the domestic like product.

On November 1, 2023, Commerce received an adequate substantive response to the *Initiation Notice* from the domestic interested party within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive responses from any other interested parties, and no interested party requested a hearing. On November 17, 2023, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties, and that Commerce would conduct an expedited (120-day) sunset review of the *Order,*[5] pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)–(C).

Scope of the Order

The product covered by the *Order* is sodium gluconate from China. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of the continuation or recurrence of subsidization in the event of revocation of the *Order* and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is provided in the accompanying Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNotices/ListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, we determine that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the

[1] *See Sodium Gluconate, Gluconic Acid and Derivative Products from the People's Republic of China: Antidumping and Countervailing Duty Orders,* 83 FR 56299 (November 13, 2018) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 88 FR 67729 (October 2, 2023).

[3] *See* Domestic Interested Parties' Letter, ''Sodium Gluconate, Gluconic Acid, and Derivative Products from the People's Republic of China—Domestic Interested Parties' Notice of Intent to Participate,'' dated October 12, 2023.

[4] *See* Domestic Interested Parties' Letter, ''Sodium Gluconate, Gluconic Acid, and Derivative Products from the People's Republic of China—Domestic Interested Parties' Substantive Response,'' dated November 1, 2023.

[5] *See* Commerce's Letter, ''Sunset Reviews Initiated on October 2, 2023,'' dated November 17, 2023.

[6] *See* Memorandum, ''Decision Memorandum for the Final Results of the First Expedited Sunset Review of the Antidumping Duty Orders on Sodium Gluconate, Gluconic Acid and Derivative Products from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

following net countervailable subsidy rates:

Company	Subsidy rate (percent *ad valorem*)
Qingdao Dongxiao Enterprise Co., Ltd	194.67
Shandong Fuyang Biotechnology Co	194.67
Shandong Kaison Biochemical Co Ltd	194.67
Tongxiang Hongyu Chemical Co., Ltd	194.67
All Others	194.67

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

Commerce is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: January 29, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2024–02116 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Artificial Intelligence Advisory Committee

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) announces that the National Artificial Intelligence Advisory Committee (NAIAC or Committee) will hold an open meeting in-person and virtually via web conference on February 22, 2024, from 9 a.m.–4 p.m. eastern time. The primary purpose of this meeting is for the Committee to report working group findings, identify actionable recommendations, receive public briefings and receive an update from the NAIAC Law Enforcement Subcommittee. The final agenda will be posted to the NAIAC website: *ai.gov/naiac/.*

DATES: The meeting will be held on Thursday, February 22, 2024, from 9 a.m.–4 p.m. eastern time.

ADDRESSES: The meeting will be held in-person and virtually via web conference from the U.S. Department of Commerce, Herbert C. Hoover Federal Building, located at 1401 Constitution Ave. NW, Washington, DC 20230. For instructions on how to attend and/or participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Alicia Chambers, Committee Liaison Officer, National Institute of Standards and Technology, 100 Bureau Drive, MS 8900, Gaithersburg, MD 20899, *alicia.chambers@nist.gov* or 301–975–5333, or Cheryl Gendron, Designated Federal Officer, National Institute of Standards and Technology, 100 Bureau Drive, MS 8900, Gaithersburg, MD 20899, *cheryl.gendron@nist.gov.* Please direct any inquiries to *naiac@nist.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. 1001 *et seq.,* notice is hereby given that the NAIAC will meet on Thursday, February 22, 2024, from 9 a.m.–4 p.m. eastern time. The meeting will be open to the public and will be held in-person and virtually via web conference. The primary purpose of this meeting is for the Committee to report working group findings, identify actionable recommendations, receive public briefings and receive an update from the NAIAC Law Enforcement Subcommittee. The final agenda and meeting time will be posted to the NAIAC website: *https://www.nist.gov/itl/national-artificial-intelligence-advisory-committee-naiac.*

The NAIAC is authorized by section 5104 of the National Artificial Intelligence Initiative Act of 2020 (Pub. L. 116–283), in accordance with the provisions of the Federal Advisory Committee Act, as amended (FACA), 5 U.S.C. 1001 *et seq.* The Committee advises the President and the National Artificial Intelligence Initiative Office on matters related to the National Artificial Intelligence Initiative. Additional information on the NAIAC is available at *ai.gov/naiac/.*

Comments: The National Artificial Intelligence Advisory Committee (NAIAC) Workforce and Opportunity Working Group seeks public feedback into ways the nation can support people's lifetime employment and career success as they navigate changes in jobs and the economy brought on by AI, automation, and other factors. The Working Group would appreciate receiving expressions of interest in participating in public dialogues throughout 2024 addressing the following:

1. Perspectives from workers on the impact of automation, AI, and other factors in their lives, jobs, and careers. This could include feedback on the nature and quality of support programs and resources available to them and ideas for how employers, government, and other stakeholders can help them today.

2. Ideas for new frontiers for supporting workers, career pathways, and otherwise expanding opportunity as AI changes the economy and nature of work. This could include: explaining data and knowledge gaps that, if closed, would help workers, organizations, policymakers, and others make better, data-informed decisions; and, elaborating on nascent ideas and innovations with the potential for national impact and scale.

Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee's agenda for this meeting are invited to submit comments in advance of the meeting. Approximately ten minutes will be reserved for public comments, which will be read on a first-come, first-served basis. Please note that all comments submitted via email will be treated as public documents and will be made available for public inspection. All comments must be submitted via email with the subject line ''February 22,

2024, NAIAC Meeting Comments'' to *naiac@nist.gov* by 5 p.m. eastern Time, Tuesday, February 20, 2024. NIST will not accept comments accompanied by a request that part or all of the comment be treated confidentially because of its business proprietary nature or for any other reason. Therefore, do not submit confidential business information or otherwise sensitive, protected, or personal information, such as account numbers, Social Security numbers, or names of other individuals.

Virtual Admittance Instructions: The meeting will be broadcast virtually via web conference. Registration is required to view the web conference. Instructions to register will be made available on NAIAC Meeting Information website. Registration will remain open until the conclusion of the meeting.

In-Person Admittance Instruction: Limited space is available on a first-come, first-served basis for anyone who wishes to attend in person. Registration is required for in-person attendance. Registration details will be posted at NAIAC Meeting Information website. Registration for in-person attendance will close at 5 p.m. eastern time on Tuesday, February 20, 2024.

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2024–02086 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Assessing Public Preferences and Values To Support Coastal and Marine Management

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on August 25, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: Assessing Public Preferences and Values to Support Coastal and Marine Management.

OMB Control Number: 0648–XXXX.

Form Number(s): None.

Type of Request: New information collection.

Number of Respondents: Focus groups: 96; Surveys: 6,282.

Average Hours per Response: Focus groups: 1 hour; Surveys: 12 minutes.

Total Annual Burden Hours: 3,528.48.

Needs and Uses: This request is for a new information collection, which will include focus groups and pre-test to help guide revisions necessary to the survey instrument, to directly support decision-makers with the National Estuarine Research Reserve (NERR). The proposed data collection involves surveying randomly selected residents (aged 18 years and older) from households in counties surrounding the NERRs. The purpose of this information collection is to obtain data on the opinions, values, attitudes, and behaviors of visitors to NOS-special places, as well as residents from surrounding areas. The initial surveys will be conducted for the Chesapeake Bay National Estuarine Research Reserve in Virginia (CBNERR–VA), Weeks Bay NERR (WBNERR), and Grand Bay NERR (GNDNERR), and the survey will be repeated regularly in other NERRs based on information needs and budget.

The NERRS is a Federal-State partnership program for the stewardship, education, and research of unique estuarine sites. This data collection supports the NERRS' vision of establishing healthy estuaries and coastal watersheds where human and ecological communities thrive. The NERRS has identified five priority research areas, including a focus on social science and economic processes within each NERR site. However, limited data exist characterizing stakeholder activities, attitudes, knowledge, and preferences, including their spatial aspects. Gathering such data is essential for effective management of stakeholder groups, regulatory proposals, and resource management decisions.

Designated in 1986, WBNERR is located along the eastern shore of Mobile Bay in Baldwin County, Alabama. CBNERR–VA, designated in 1991, comprises four reserve sites within the York River in the southern Chesapeake Bay subregion. Finally, GNDNERR was established in 1999 and is located in the Grand Bay Savannah Complex along the Mississippi-Alabama state line in Jackson County, Mississippi. All three NERRS prioritize public access and responsible use to protect ecosystems, identifying public sites, minimizing conflicts, and evaluating visitor use. Therefore, information is needed on who uses these NERR sites, their motivations, management preferences, and why some do not visit. This data supports conservation and management goals, strengthens decision-making, increases capacity, and extends education and outreach. It is also required by NOAA to meet objectives related to ocean and coastal planning and management. The data benefits state and local officials as well.

NOAA's mission is to provide science, service and stewardship for, among other activities, management of the nation's oceans and coasts. NOAA supports ''comprehensive ocean and coastal planning and management'' in order to facilitate use of oceans and coasts, while also ensuring ''continued access to coastal areas, sustained ecosystems, maintained cultural heritage, and limited cumulative impacts.'' NOAA is subject to and supports mandates of the Coastal Zone Management Act (CZMA) (16 U.S.C. 1452 (303)(2)(D)), which encourages the wise use of coastal resources, including energy activity. The CZMA also encourages the inclusion and participation of the public in carrying out the tenets of the act (16 U.S.C. 1452 (303)(4)). The National Environmental Policy Act (NEPA) (40 CFR 1502.6) mandates federal agencies to use social science data to assess the impacts of federal actions on the human environment. Consequently, up-to-date sociological data is needed to support federal agency obligations under each of these acts.

Finally, NOAA is responding to Executive Orders 13707 and 13985. Executive Order 13707, Using Behavioral Science Insights to Better Serve the American People, requests federal agencies to, among other actions: ''identify policies, programs, and operations where applying behavioral science insights may yield substantial improvements in public welfare, program outcomes, and program cost effectiveness'' and ''develop strategies for applying behavioral science insights to programs and, where possible, rigorously test and evaluate the impact of these insights.'' Executive Order 13985, On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, requires the federal government to allocate resources ''in a manner that

increases investment in underserved communities, as well as individuals from those communities.''

Affected Public: Individuals or households.

Frequency: This is a one-time information collection for this region, although the collection may be deployed to other regions in the future.

Respondent's Obligation: Voluntary.

Legal Authority: Coastal Zone Management Act (CZMA) (16 U.S.C. 1452 (303)(2)(D)), National Environmental Policy Act (NEPA) (40 CFR 1502.6).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–02141 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–JS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Transshipment Requirements Under the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to Office of Management and Budget (OMB).

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before April 2, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0649 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Emily Reynolds, Fishery Policy Analyst, NOAA Fisheries, 1845 Wasp Blvd., Bldg. #176, Honolulu, HI 96818, (808)–725–5039, *emily.reynolds@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a currently approved information collection. National Marine Fisheries Service (NMFS) has issued regulations under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFCIA; 16 U.S.C. 6901 *et seq.*) to carry out the obligations of the United States under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention), including implementing the decisions of the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC or Commission). The regulations include requirements for the owners and operators of U.S. vessels to: (1) complete and submit a Pacific Transshipment Declaration form for each transshipment that takes place in the area of application of the Convention (Convention Area) of highly migratory species caught in the Convention Area, (2) submit notice to the WCPFC Executive Director containing specific information at least 36 hours prior to each transshipment on the high seas in the Convention Area, (3) in the event that a vessel anticipates a transshipment where an observer is required, provide notice to NMFS at least 72 hours before leaving port of the need for an observer, (4) complete and submit a U.S. Purse Seine Discard form within 48 hours after any discard, (5) submit daily purse seine fishing effort reports; (6) submit a notice to a contact designated by NMFS in the event of a serious illness, assault, harassment, intimidation or threat to a WCPFC observer; and (7) submit notice to obtain a WCPFC observer for a purse seine vessel departing from American Samoa.

The information collected from these requirements is used by NOAA and the Commission to help ensure compliance with domestic laws and the Commission's conservation and management measures, and are necessary in order for the United States to satisfy its obligations under the Convention. There are no changes to this collection.

II. Method of Collection

Respondents must submit some of the information by mail or in person via paper forms and must submit other information electronically by fax or email.

III. Data

OMB Control Number: 0648–0649.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit organizations; individuals or households.

Estimated Number of Respondents: 203.

Estimated Time per Response: Transshipment Report: 60 minutes; Notice for Transshipment: 15 minutes; Pre-trip Notification for Observer Placement: 1 minute; Purse Seine Discard Report: 30 minutes; Purse Seine Fishing Activity Information: 10 minutes; Observer Safety Notification: 5 minutes; Pre-trip Notification for Purse Seine Vessels requesting a WCPFC observer: 5 minutes.

Estimated Total Annual Burden Hours: 959.

Estimated Total Annual Cost to Public: $5,494.

Respondent's Obligation: Mandatory.

Legal Authority: WCPFCIA; 16 U.S.C. 6901 *et seq.*

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality,

utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this Information Collection Request (ICR). Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–02075 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD674]

Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish of the Gulf of Alaska; Central Gulf of Alaska Rockfish Program

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

ACTION: Notification of standard prices and fee percentage.

SUMMARY: NMFS publishes the standard ex-vessel prices and fee percentage for cost recovery under the Central Gulf of Alaska (GOA) Rockfish Program (Rockfish Program). This action is intended to provide participants in a rockfish cooperative with the standard prices and fee percentage for the 2023 fishing year, which was authorized from May 1 through November 15. The fee percentage is 3.00 percent. The fee payments are due from each rockfish cooperative on or before February 15, 2024.

DATES: *Valid on:* February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Charmaine Weeks, 907–586–7105.

SUPPLEMENTARY INFORMATION:

Background

The rockfish fisheries are conducted in Federal waters near Kodiak, Alaska by trawl and longline vessels. Regulations implementing the Rockfish Program are set forth at 50 CFR part 679. Exclusive harvesting privileges are allocated as quota share under the Rockfish Program for rockfish primary and secondary species. Each year, NMFS issues rockfish primary and secondary species cooperative quota (CQ) to rockfish quota shareholders to authorize harvest of these species. The rockfish primary species are northern rockfish, Pacific Ocean perch, and dusky rockfish. The rockfish secondary species include Pacific cod, rougheye rockfish, shortraker rockfish, sablefish, and thornyhead rockfish. Rockfish cooperatives began fishing under the Rockfish Program in 2012.

The Rockfish Program is a limited access privilege program established under the provisions of section 303A of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Sections 303A and 304(d) of the Magnuson-Stevens Act require NMFS to collect fees to recover the actual costs directly related to the management, data collection and analysis, and enforcement of any limited access privilege program. Therefore, NMFS is required to collect fees for the Rockfish Program under sections 303A and 304(d)(2) of the Magnuson-Stevens Act. Section 304(d)(2) of the Magnuson-Stevens Act also limits the cost recovery fee so that it may not exceed 3.00 percent of the ex-vessel value of the fish harvested under the Rockfish Program.

Standard Prices

NMFS calculates cost recovery fees based on standard ex-vessel value prices, rather than actual price data provided by each rockfish CQ holder. Use of standard ex-vessel prices is allowed under sections 303A and 304(d)(2) of the Magnuson-Stevens Act. NMFS generates a standard ex-vessel price for each rockfish primary and secondary species on a monthly basis to determine the average price paid per pound for all shoreside processors receiving rockfish primary and secondary species CQ. Rockfish processors that receive and purchase landings of rockfish CQ groundfish must submit, on an annual basis, a volume and value report for the period May 1 to November 15 (50 CFR 679.5(r)(10)(ii)).

Regulations at 50 CFR 679.85(b)(2) require the Regional Administrator to publish rockfish standard ex-vessel values during the first quarter of each calendar year. The standard prices are described in U.S. dollars per pound for rockfish primary and secondary species CQ landings made during the previous year.

Fee Percentage

NMFS assesses a fee on the standard ex-vessel value of rockfish primary species and rockfish secondary species CQ harvested by rockfish cooperatives in the Central GOA and waters adjacent to the Central GOA when rockfish primary species caught by a cooperative are deducted from the Federal total allowable catch. The rockfish entry level longline fishery and trawl vessels that opt out of joining a cooperative are not subject to cost recovery fees because those participants do not receive rockfish CQ. Specific details on the Rockfish Program's cost recovery provision may be found in the implementing regulations set forth at 50 CFR 679.85.

NMFS informs—by letter—each rockfish cooperative of the fee percentage applied to the previous year's landings and the total amount due. Fees are due on or before February 15 of each year. Failure to pay on time will result in the permit holder's rockfish quota share becoming non-transferable, and the person will be ineligible to receive any additional rockfish quota share by transfer. In addition, cooperative members will not receive any rockfish CQ the following year until full payment of the fee is received by NMFS.

NMFS calculates and publishes in the **Federal Register** the fee percentage in the first quarter of each year according to the factors and methods described in Federal regulations at 50 CFR 679.85(c)(2). NMFS determines the fee percentage that applies to landings made in the previous year by dividing the total Rockfish Program management, data collection and analysis, and enforcement costs (direct program costs) during the previous year by the total standard ex-vessel value of the rockfish primary species and rockfish secondary species for all rockfish CQ landings made during the previous year (fishery value). NMFS captures the direct program costs through an established accounting system that allows staff to track labor, travel, contracts, rent, and procurement. Fee collections in any given year may be less than or greater than the direct program costs and fishery value for that year, as the fee percentage is established by regulation in the first quarter of the calendar year based on the program costs and the

fishery value of the previous calendar year.

Using the fee percentage formula described above, the estimated percentage of program costs to value for the 2023 calendar year is 3.59 percent of the standard ex-vessel value; since this is higher than the regulatory cap, the fee percentage is the capped 3.00 percent. Program costs for 2023 increased by 11.40 percent compared to 2022 costs; however, the fishery value decreased approximately 21.30 percent resulting in a higher fee percentage. Similar to 2022, the majority of 2023 costs were a result of direct personnel and contract costs.

Species	Month	Average price/lb
Dusky Rockfish	May	$0.14
	June	0.11
	July	0.12
	Aug	0.12
	September	0.12
	October	0.10
	November	0.12
Northern Rockfish	May	0.14
	June	0.13
	July	0.13
	Aug	0.13
	September	0.13
	October	0.13
	November	0.13
Pacific Cod	May	0.37
	June	0.37
	July	0.33
	Aug	0.33
	September	0.33
	October	0.28
	November	0.33
Pacific Ocean Perch	May	0.14
	June	0.14
	July	0.13
	Aug	0.13
	September	0.13
	October	0.09
	November	0.13
Rougheye Rockfish	May	0.11
	June	0.10
	July	0.10
	Aug	0.10
	September	0.10
	October	0.10
	November	0.10
Sablefish	May	0.75
	June	0.81
	July	0.69
	Aug	0.69
	September	0.69
	October	0.69
	November	0.69
Shortraker Rockfish	May	0.13
	June	0.19
	July	0.15
	Aug	0.15
	September	0.15
	October	0.15
	November	0.15
Thornyhead Rockfish	May	0.40
	June	0.40
	July	0.39
	Aug	0.39
	September	0.39
	October	0.39
	November	0.39

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.;* Pub. L. 108–447; Pub. L. 111–281.

Dated: January 29, 2024.

Everett Wayne Baxter,

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

[FR Doc. 2024–02067 Filed 2–1–24; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete product(s) and service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: March 3, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404 or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) and service(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
8460–01–113–7575—Envelope Case, Map and Photograph
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s):
6545–01–525–9821—Mass Casualty Case
6545–01–526–0062—Splint Module
6545–01–526–0423—Mass Casualty First Aid Kit
Designated Source of Supply: Chautauqua County Chapter, NYSARC, Jamestown, NY
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s):
6135–00–904–6780—Battery, Non-Rechargeable, Button, 1.55V, Silver Oxide, NEDA 1133SO, EA/1
Designated Source of Supply: Eastern Carolina Vocational Center, Inc., Greenville, NC
Contracting Activity: DLA LAND AND MARITIME, COLUMBUS, OH

Service(s)

Service Type: Janitorial/Custodial
Mandatory for: US Army Reserve, PFC Schooley USARC, AMSA 89, 125A Armory Road Galax, VA
Designated Source of Supply: Mount Rogers Community Services Board, Wytheville, VA
Contracting Activity: DEPT OF THE ARMY, W6QK ACC–PICA

Michael R. Jurkowski,

Acting Director, Business Operations.

[FR Doc. 2024–02083 Filed 2–1–24; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 9:00 a.m. EST, Friday, February 9, 2024.

PLACE: Virtual meeting.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement and examination matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.cftc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

Authority: 5 U.S.C. 552b.

Dated: January 31, 2024.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2024–02271 Filed 1–31–24; 4:15 pm]

BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2024–FSA–0021]

Privacy Act of 1974; System of Records

AGENCY: Federal Student Aid, U.S. Department of Education.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the U.S. Department of Education (Department) publishes this notice of a modified system of records entitled ''Aid Awareness and Application Processing'' (18–11–21). This system maintains information necessary for the Department to process applications for Federal student financial program assistance under title IV of the Higher Education Act of 1965, as amended (HEA); to perform the responsibilities of the Federal Student Aid (FSA) Ombudsman; to provide Federal student loan repayment relief including under the borrower defense to repayment regulations; to notify aid applicants and aid recipients of aid program opportunities and updates under title IV of the HEA via digital communication channels; and to maintain the *StudentAid.gov* website as the front end for assisting customers with all of their Federal student financial aid needs throughout the student aid lifecycle. The Department's Digital and Customer Care (DCC) Information Technology (IT) system collects the electronic records maintained in the Aid Awareness and Application Processing (AAAP) system.

DATES: Submit your comments on this modified system of records notice on or before March 4, 2024.

This modified system of records notice will become applicable on February 2, 2024, unless it needs to be changed as a result of public comment, except for the modified routine use (1)(a) that is outlined in the section entitled ''ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES,'' which will be applicable on March 4, 2024, unless it needs to be changed as a result of public comment. The Department will publish any changes to the modified system of records notice resulting from public comment.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at *regulations.gov*. However, if you require an accommodation or cannot otherwise submit your comments via *regulations.gov,* please contact one of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**. The Department will not accept comments submitted by fax or by email, or comments submitted after the comment period closes. To ensure that the Department does not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*,

including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the ''FAQ'' tab.

Privacy Note: The Department's policy is to make comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *http://www.regulations.gov*. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or aid, please contact one of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Rachel Coghlan, Central Processing System—System Manager, Student Experience and Aid Delivery, Federal Student Aid (FSA), U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454. Telephone: 202–377–3205. Email: *Rachel.Coghlan@ed.gov*.

Corey Johnson, FAFSA Processing System (FPS) Information System Owner, Federal Student Aid, U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454. Telephone: 202–377–3898. Email: *Corey.Johnson@ed.gov*.

Bonnie Latreille, Ombudsman/Director, Ombudsman Group, Federal Student Aid (FSA), U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454. Telephone: 202–377–3726. Email: *Bonnie.J.Latreille@ed.gov*.

Pardu Ponnapalli, Information System Owner, Technology Directorate, Federal Student Aid, U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454. Telephone: 240–382–5825. Email: *Pardu.Ponnapalli@ed.gov*.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act, the Department proposes to modify the system of records notice entitled ''Aid Awareness and Application Processing'' (18–11–21).

The Department is modifying routine use (1)(a) of the section entitled ''ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES'' to add ''applicants'' to the list of individuals and entities to whom the Department may disclose records from the system for the purposes described therein.

Accessible Format: On request to any of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Richard Cordray,

Chief Operating Officer, Federal Student Aid.

For the reasons discussed in the preamble, the Chief Operating Officer, Federal Student Aid (FSA) of the U.S. Department of Education (Department) publishes a modified system of records notice to read as follows:

SYSTEM NAME AND NUMBER:

Aid Awareness and Application Processing (18–11–21).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

U.S. Department of Education, 830 First Street NE, Washington, DC 20202.

The following locations are for the Central Processing System (CPS):

Lee's Summit Federal Records Center, National Archives and Records Administration (NARA), 200 Space Center Drive, Lee's Summit, MO 6464–1182 (*Note:* This is where paper applications are stored);

General Dynamics Information Technology (GDIT) Image and Data Capture (IDC) Center, 1084 South Laurel Road, Building 1, London, KY 40744 (*Note:* The IDC scans paper financial aid documents and correspondence, key-enters the data and electronically transmits the data and related images to the CPS for processing);

Next Generation Data Center (NGDC), 250 Burlington Drive, Clarksville, VA 23927 (*Note:* NGDC hosts the infrastructure that supports CPS applications including backend application processing); and

CPS Print Facility, 327 Columbia Pike, Rensselaer, NY 12144 (*Note:* This facility handles print operations).

The following locations are for the Free Application for Federal Student Aid (FAFSA®) Processing System (FPS):

Perspecta/Peraton, 15052 Conference Center Drive, Chantilly, VA 20151 (*Note:* Perspecta supports the FSA-provided development, security, and operations (DevSecOps) toolchain configuration; coordinates environment building; and supports technical operations activities and application modernization);

Information Capture Solutions (ICS), 25 Air Park Drive, London, KY 40744 (*Note:* ICS provides image and data capture, print/mailing operational services, and builds and operates the IDC);

iWorks, 1889 Preston White Drive, Suite 100, Reston, VA 20191 (*Note:* iWorks provides quality control managers (key personnel); develops and updates the quality control plan; oversees/validates service level measures; supports internal Capability Maturity Model Integration (CMMI) audits; supports Project Management Office (PMO) activities; and provides application development support using Agile methodologies);

Red Cedar Consultancy, LLC, 161 Fort Evans Road NE, Suite 200, Leesburg, VA 20176 (*Note:* Red Cedar provides application development support using Agile methodologies);

Windsor Group, LLC, 6820 Wisconsin Avenue, Unit 4004, Chevy Chase, MD 20815 (*Note:* Windsor Group provides quality resources in system security, database administration, and technical writing); and

Jazz Solutions, LLC, 20745 Williamsport Place, Suite 320, Ashburn, VA 20147 (*Note:* Jazz Solutions provides application development support using

Agile methodologies and supports application programming interface (API) management solutions, including designing, building, and operating services).

The following locations are for the Digital and Customer Care (DCC) Information Technology (IT) System:

Salesforce Government Cloud, 415 Mission Street, 3rd Floor, San Francisco, CA 94105 (*Note:* The system is accessible via the internet to different categories of users, including Department personnel, customers, and designated agents of the Department at any location where they have internet access. This site is the location where customer interactions with contact center support via all inbound and outbound channels (phone, email, chat, webform, email, customer satisfaction survey, fax, physical mail, and controlled correspondence) and customer-provided feedback (complaints, suspicious activities, positive feedback, and dispute cases) are tracked and worked by contractors and the Department. This site also contains workflow management for processing tasks including, but not limited to: credit appeals, borrower defense to repayment, commingled Social Security numbers (SSNs), and archived document retrieval in the Common Origination and Disbursement (COD) System, and the FAFSA special correction application process. This site stores customer-provided documentation to support the interactions and processing tasks, as needed. This site will also be used by the Department for determining employer eligibility to support Public Service Loan Forgiveness (PSLF), and Office of Inspector General (OIG) fraud referrals);

Amazon Web Services (AWS) GovCloud (East/West), 410 Terry Avenue, North Seattle, WA 98109–5210 (*Note:* The DCC IT system is hosted at this location. This site is the location where the Shado (Dynamo) application collects, processes, stores, and makes available user activity events from across the DCC IT system to provide a complete view of the customer to the Department and its contractors. This site is also the location where the Adobe Marketing Campaign application delivers strategic and real-time personalized email and short message service (SMS) communications); and

Contact Center Fulfillment Center (Senture facility), 4255 W. Highway 90, Monticello, KY 42633 (*Note:* This facility handles mail fulfillment and imaging operations).

The following 10 listings are the locations of the Aid Awareness and Application Processing Customer Contact Centers: Jacksonville Contact Center, One Imeson Park Boulevard, Jacksonville, FL 32118; Knoxville, TN Servicing Center, 120 N Seven Oaks Drive, Knoxville, TN 37922; 1600 Osgood Street, Suite 2–120, North Andover, MA 01845; 11499 Chester Road, Suite 101, Sharonville, OH 45246; 100 Domain Drive, Suite 200, Exeter, NH 03833; 221 N Kansas Street, Suite 700, El Paso, TX 79901; 4255 W Highway 90, Monticello, KY 42633; 555 Vandiver Drive, Columbia, MO 65202; 633 Spirit Drive, Chesterfield, MO 63005; and 820 First Street NE, Washington, DC 20002.

SYSTEM MANAGER(S):

CPS—System Manager, Student Experience and Aid Delivery, FSA, U.S. Department of Education, Union Center Plaza (UCP), 830 First Street NE, Washington, DC 20202–5454.

FPS—Information System Owner, Technology Directorate, Federal Student Aid, U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454.

Ombudsman, FSA, U.S. Department of Education, UCP, 830 First Street NE, Washington, DC 20202–5454.

DCC—Information System Owner, Technology Directorate, Federal Student Aid, U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority is: title IV of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070 *et seq.*); 20 U.S.C. 1018(f); and the Higher Education Relief Opportunities for Students Act of 2003 (20 U.S.C. 1098bb) (including any waivers or modifications that the Secretary of Education deems necessary to make to any statutory or regulatory provision applicable to the Federal student financial assistance programs under title IV of the HEA to achieve specific purposes listed in the section in connection with a war, other military operation, or a national emergency). The collection of SSNs of individuals, and parents of dependent students, who apply for or receive Federal student financial assistance under programs authorized by title IV of the HEA is also authorized by 31 U.S.C. 7701 and Executive Order 9397, as amended by Executive Order 13478 (November 18, 2008).

PURPOSE(S) OF THE SYSTEM:

The information contained in this system is maintained for the following purposes related to applying for Federal student financial assistance and administering title IV, HEA programs: (*Note:* Different parts of the HEA use the terms ''discharge,'' ''cancellation,'' or ''forgiveness'' to describe when a borrower's loan amount is reduced in whole or in part by the Department. To reduce complexity, this system of records notice uses the term ''discharge'' to include all three terms (''discharge,'' ''cancellation,'' and ''forgiveness''), including but not limited to discharges of student loans made pursuant to specific benefit programs. At times, the system of records notice may refer by name to a specific benefit program, such as the ''Public Service Loan Forgiveness'' program; such specific references are not intended to exclude any such program benefits from more general references to loan discharges.)

(1) Assisting with the determination, correction, processing, tracking, and reporting of program eligibility and benefits for the Federal student financial assistance programs authorized by title IV of the HEA, including, but not limited to, discharge of eligible loans under title IV, HEA programs;

(2) Making a loan or grant;

(3) Verifying the identity of the applicant for Federal financial assistance under title IV of the HEA, the spouse of a married applicant, the parent(s) of a dependent applicant, and, until CPS is decommissioned after September 30, 2024, an individual who applies for an FSA ID; and verifying the accuracy of the information in this system;

(4) Reporting the results of the need analysis and Federal Pell Grant eligibility determination to applicants, institutions of higher education (IHEs), third-party servicers, State agencies designated by the applicant, and Departmental and investigative components;

(5) Reporting the results of duly authorized matching programs between the Department and other Federal agencies and between the Department and State or local governments, or agencies thereof, to applicants, IHEs, third-party servicers, State agencies designated by the applicant, and Departmental and investigative components where the Department is required by law to do so or where it would be essential to the conduct of the matching program to report, such as for the imposition of criminal, civil, or administrative sanctions;

(6) Enforcing the terms and conditions of a title IV, HEA loan or grant;

(7) Servicing and collecting a delinquent title IV, HEA loan or grant;

(8) Initiating enforcement action against individuals, IHEs, or other

entities involved in program fraud, abuse, or noncompliance;

(9) Locating a debtor or recipient of a grant overpayment;

(10) Maintaining a record of the data supplied by those requesting title IV, HEA program assistance;

(11) Ensuring compliance with and enforcing title IV, HEA programmatic requirements and various consumer protection laws;

(12) Acting as a repository and source for information necessary to fulfill the requirements of title IV of the HEA;

(13) Evaluating title IV, HEA program effectiveness;

(14) Enabling IHEs and State grant agencies designated by the applicant to review and analyze the financial aid data of their applicant population;

(15) Enabling IHEs and State grant agencies to assist applicants with the completion of the application for the Federal student financial assistance programs authorized by title IV of the HEA;

(16) Assisting State agencies, eligible IHEs, and other entities that award aid to students and that are designated by the Secretary of Education with making eligibility determinations for the award of aid and with administering these awards; and

(17) Promoting and encouraging applications for title IV, HEA program assistance, State assistance, and aid awarded by eligible IHEs or by other entities designated by the Secretary of Education.

The information contained in this system is also maintained for the following purposes related to managing customer engagement:

(1) Carrying out the duties and responsibilities of the FSA Ombudsman, including investigating and resolving complaints, inquiries, and requests for assistance, updating borrower account records, correcting errors, analyzing complaint trends, and making appropriate recommendations pursuant to 20 U.S.C. 1018(f);

(2) Carrying out the duties and responsibilities of the Department to provide Federal student loan repayment relief under Federal law;

(3) Verifying the identity of FSA customers;

(4) Recording complaints, suspicious activities, positive feedback, and comments as provided by customer interactions with contact center support via inbound and outbound channels (phone, chat, webform, email, customer satisfaction survey, fax, physical mail, social media platforms, digital engagement platforms, and controlled correspondence);

(5) Tracking individual cases, including complaints, borrower defense submissions, general inquiries, and chat sessions, through final resolution, reporting trends, and analyzing the data to recommend improvements in Federal student financial assistance programs;

(6) Assisting in the informal resolution of disputes submitted by aid applicants or aid recipients about issues related to title IV, HEA program assistance;

(7) Carrying out the duties and responsibilities of the Department under the borrower defense to repayment regulations at 34 CFR 685.206 and 685.222 and 34 CFR part 685, subpart D, including receiving, reviewing, evaluating, and processing requests for relief under the borrower defense to repayment regulations; and

(8) Initiating proceedings, where appropriate, to recover liabilities from an IHE for losses incurred as a result of the act or omission of the IHE participating in the Federal student loan programs.

The information contained in this system is also maintained for the following purposes related to assisting aid applicants and recipients with Federal student financial assistance programs authorized by title IV of the HEA, and managing customer relationships for marketing and improving customer service:

(1) Determining employer qualification for borrowers to receive discharge under the PSLF Program;

(2) Collecting, processing, storing, and making available user activity events and user-submitted documentation from across the DCC IT system to provide a complete view of the customer to the Department and its contractors;

(3) Sending aid applicants and aid recipients strategic and real-time, personalized communications via email, and SMS ''text messages'' via mobile phone communications to inform them of title IV, HEA aid marketing campaigns (such as encouraging completion of their FAFSA), and sending transactional communication to customers (such as confirmation emails when a user completes an action);

(4) Measuring customer satisfaction and analyzing results; and

(5) Promoting and encouraging the repayment of title IV, HEA program loans in a timely manner.

The information in this system is also maintained for the following purposes relating to the Department's administration and oversight of title IV, HEA programs:

(1) To support the investigation of possible fraud and abuse and to detect and prevent fraud and abuse in the title IV, HEA Federal grant and loan programs;

(2) To support compliance with title IV, HEA statutory and regulatory requirements;

(3) To provide an aid recipient's financial aid history, including information about the recipient's title IV, HEA loan defaults, title IV, HEA aid receipt, and title IV, HEA grant program overpayments;

(4) To facilitate receiving and correcting application data, processing Federal Pell Grants and Direct Loans, and reporting Federal Perkins Loan Program expenditures to the Department's processing and reporting systems;

(5) To support pre-claims/supplemental pre-claims assistance;

(6) To assist in locating holders of title IV, HEA loan(s);

(7) To assist in assessing the administration of title IV, HEA program funds by guaranty agencies, lenders and loan holders, IHEs, and third-party servicers;

(8) To initiate or support a limitation, suspension, or termination action, an emergency action, or a debarment or suspension action;

(9) To inform the parent(s) of a dependent applicant of information about the parent(s), or the spouse of a married applicant of information about the spouse, in an application for title IV, HEA funds;

(10) To disclose applicant records to the parent(s) of a dependent applicant applying for a PLUS loan (to be used on behalf of a student), to identify the student as the correct beneficiary of the PLUS loan funds, and to allow the processing of the PLUS loan application and promissory note;

(11) To expedite the application process;

(12) To enable an applicant, at the applicant's written request, to obtain income information about the applicant from the Internal Revenue Service (IRS) using the Data Retrieval Tool, until CPS is decommissioned after September 30, 2024;

(13) To identify, prevent, reduce, and recoup improper payments, prevent fraud, and conduct at-risk campaigns, including protecting customers from Third-Party Debt Relief firms;

(14) To help Federal, State, Tribal, and local government entities exercise their supervisory and administrative powers (including, but not limited to licensure, examination, discipline, regulation, or oversight of educational institutions, Department contractors, guaranty agencies, lenders and loan holders, and third-party servicers) or to respond to individual aid applicant or

recipient complaints submitted regarding the practices or processes of the Department and/or the Department's contractors, or to update information or correct errors contained in Department records regarding the aid applicant's or recipient's title IV, HEA program funds;

(15) To provide eligible applicants for title IV, HEA aid, and when necessary, the spouse or parents of an applicant, with information about certain Federal means-tested benefits and services for which they may qualify;

(16) To collect, track, and process Office of Inspector General (OIG) fraud referrals;

(17) To support research, analysis, and development, and the implementation and evaluation of educational policies in relation to title IV, HEA programs; and

(18) To conduct testing, analysis, or take other administrative actions needed to prepare for or execute programs under title IV of the HEA.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains records on individuals who are, were, or may be participants in any of the Federal student financial assistance programs under title IV of the HEA who request assistance from the Department, directly or through State requestors and legal assistance organizations (''third-party requestors'') who may request that the Secretary of Education form a group of Federal student loan borrowers for borrower defense relief. In addition, this system maintains records on individuals who are students in attendance at a secondary school, as defined under 20 U.S.C. 7801(45), for which State grant agencies and other eligible requesting entities such as secondary schools, local educational agencies (LEAs), and Tribal agencies or other designated entities that have an established relationship with the student pursuant to the terms and conditions of the Student Aid Internet Gateway (SAIG) Participation Agreement for State Grant Agencies, submit information (*e.g.,* name, date of birth (DOB), and zip code) to the Department in order for the Department to provide such entities with the student's FAFSA filing status information to promote and encourage the student to apply for title IV, HEA program assistance, State assistance, and aid awarded by IHEs or by other entities designated by the Secretary of Education, as currently permitted by Section 483(a)(3)(E) of the HEA (20 U.S.C. 1090(a)(3)(E)) through June 30, 2024.

This system also maintains records on student and parent applicants (and their third-party preparers), as well as the spouse of a married applicant and the parent(s) of a dependent applicant, who apply for Federal student financial assistance under one of the programs authorized under title IV of the HEA, including, but not limited to the: (1) Federal Pell Grant Program; (2) Federal Perkins Loans Program; (3) Academic Competitiveness Grant (ACG) Program; (4) National Science and Mathematics Access to Retain Talent (National SMART) Grant Program; (5) Teacher Education Assistance for College and Higher Education (TEACH) Grant Program; (6) Iraq and Afghanistan Service Grant (IASG) Program; (7) Direct Loan Program, which includes Federal Direct Stafford/Ford Loans, Federal Direct Unsubsidized Stafford/Ford Loans, Federal Direct PLUS Loans, and Federal Direct Consolidation Loans; (8) Federal Family Education Loan (FFEL) Program; and (9) Federal Insured Student Loan (FISL) Program.

This system also maintains records on individuals who apply for an FSA ID in the Department's Person Authentication Service (PAS) system because the Department uses CPS, which maintains records that are part of this system, as a pass-through to send these individuals' records from the PAS system to the Social Security Administration (SSA) for computer matching in order to assist the Department in verifying their identities. This pass-through will be terminated when CPS is decommissioned after September 30, 2024.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains records that contain the following information:

(1) Information provided by applicants for title IV, HEA program assistance on an incomplete or completed FAFSA, including, but not limited to, the applicant's name, address, SSN, DOB, telephone number, driver's license number (which will not be collected on the FAFSA for award year 2024–2025 and onward, and will not be collected by FPS), email address, citizenship status, marital status, legal residence, status as a veteran, educational status, and financial information (including asset and income information). (*Note:* The Federal Tax Information (FTI) that the Department will obtain directly from the IRS under the Fostering Undergraduate Talent by Unlocking Resources for Education (FUTURE) Act, Public Law 116–91, will be maintained in a separate system of records entitled ''FUTURE Act System (FAS)'' (18–11–23) for which the Department will publish a system of records notice in the **Federal Register**);

(2) Information provided about the parent(s) of a dependent applicant, including, but not limited to, the parent's highest level of schooling completed (which will not be collected on the FAFSA starting with award year 2024–2025 and will not be collected by FPS; after which point the Department will instead collect on the FAFSA the parent's college attendance status), marital status, SSN, last name and first initial, DOB, email address, number of people in the household supported by the parent, and asset and income information.

(3) Information about the spouse of a married applicant including, but not limited to: the spouse's name, address, SSN, DOB, telephone number, email address, citizenship status, marital status, legal residence, status as a veteran, and financial information (including asset and income information that is needed for CPS processing until September 30, 2024);

(4) Information provided by IHEs on behalf of student and parent applicants, including, but not limited to, verification results, dependency overrides, and resolution of comment codes or reject codes;

(5) Information calculated by CPS through the 2023–24 award year on the applicant's expected family contribution (EFC);

(6) Information on the applicant's Institutional Student Information Record (ISIR), and Student Aid Report (SAR). The Department uses the ISIR and SAR to report, among other things, the EFC, or the SAI results that are calculated during FPS processing, to IHEs, State grant agencies, and applicants. The EFC or SAI is available to, and used by, IHEs to determine the applicant's eligibility for Federal and institutional program assistance and the amount of assistance, and State grant agencies to determine the applicant's eligibility for State grants and the amount of grant assistance. The Department notifies the applicant of the results of their application via the SAR. The Department provides the IHEs identified on the applicant's FAFSA with the ISIR, which indicates whether there are discrepant or insufficient information, school adjustments, or CPS assumptions that affect processing of the FAFSA. Other information in the system includes, but is not limited to: Secondary EFC (an EFC that is calculated from the full EFC formula and is printed in the financial aid administrator's (FAA) Information section of the ISIR), dependency status, Federal Pell Grant eligibility, duplicate SSN (an indicator that is set to alert ISIR recipients that two applications were

processed with the same SSN, Incarcerated Student Indicator Flag (an indicator that will be used to identify an aid applicant as an incarcerated student), selection for verification, Simplified Needs Test (SNT) or Automatic Zero EFC (used for extremely low family income), CPS and FPS processing comments, reject codes (explanation for applicant's FAFSA not computing EFC), assumptions made with regard to the student's information due to incomplete or inconsistent FAFSA information, FAA adjustments including dependency status overrides, and CPS and FPS record processing information (application receipt date, transaction number, transaction process date, SAR Serial Number, Compute Number, Data Release Number (DRN), a four-digit number assigned to each application), National Student Loan Database System (NSLDS) match results, a bar code, and transaction source);

(7) Information that identifies aid applicant or aid recipient complaints, positive feedback, reports of suspicious activity, requests for assistance, requests for borrower defense relief, requests for PSLF reconsideration, or other inquiries. Such information includes, but is not limited to: written documentation of an aid applicant or aid recipient's complaint, request for assistance, request for relief under the borrower defense to repayment regulations, case tracking number, case appeal identifier, or other comment or inquiry; and information pertaining to the aid recipient's or the aid recipient's parent's student financial assistance program account(s) under title IV of the HEA, such as the aid recipient's and the aid recipient's parent's names and Federal Student Aid IDs (FSA IDs). Information may include the name, address, and phone numbers of the aid recipient's counsel or representative, IHE(s), lender(s), secondary holder(s) or lender(s), guaranty agency(ies), servicer(s), private collection agency(ies), and third-party requestor(s), as this term is defined in 34 CFR 685.401(a), if applicable, and may contain other loan-level information;

(8) Information provided and generated through customer interactions with contact center support via inbound and outbound channels (phone, chat, webform, email, customer satisfaction survey, fax, physical mail, social media platforms, digital engagement platforms, and controlled correspondence). Information includes, but is not limited to: chat transcripts, email communications, audio recordings of customer calls, and screen recordings of contact center support desktop during customer interactions;

(9) Loan discharge eligibility and verification information for use in determining whether a title IV, HEA debt/loan qualifies for discharge;

(10) Aid recipient's employer information to determine employer qualification for borrowers to receive discharge under PSLF; OIG fraud referral information; and customer support interactions including phone, chat, webform, email, fax, physical mail, and controlled correspondence;

(11) Information for collecting, processing, and storing user activity events from across the DCC IT system: campaign details, delivery details, email/SMS sent timestamp, transaction ID, Federal Account Number (FAN) ID, activity details, activity date, pages/URL accessed, user IP address, user-submitted materials, and user request details;

(12) Information needed to aid in the delivery of strategic and real-time communication to customers, including, but not limited to, first name, last name, DOB, state of residence, email, phone number, mobile device ID, device data, FAFSA transaction data, uniform resource locator (URL), computer-related data, and customer communication preferences and user activity (open or clicks) for email and SMS communications;

(13) Information provided on third-party preparers, including, but not limited to, first name, last name, SSN or employer identification number, affiliation, address or employer's address, signature, and signature date.

Note: This system of records also maintains information that is collected in this system and stored in other systems of records. The following information about individuals who apply for or receive a Federal grant or loan under one of the programs authorized under title IV of the HEA is collected in this system and stored in the ''Common Origination and Disbursement (COD) System'' (18–11–02) system of records: applicant identifiers including applicant's name, SSN, and DOB; demographic information, including asset and income information (tax return status, adjusted gross income, Internal Revenue Service exemptions, and tax year), and enrollment information; borrower's loan(s) information, including information about recipients of Direct Loans, FFEL Program loans, Perkins Loans, and FISL Program loans, such as the period from the origination of the loan through final payment, and milestones, including, but not limited to, consolidation, discharge, or other final disposition including details such as loan amount, disbursements, balances, loan status, repayment plan and related information, collections, claims, deferments, forbearances, and refunds; information about students receiving Federal grants, including recipients of Pell Grants, ACG, National SMART Grants, TEACH Grants, Iraq and Afghanistan Service Grants, and including grant amounts, grant awards, verification status, lifetime eligibility used (LEU), IASG eligible veteran's dependent indicator, Children of Fallen Heroes Scholarship eligibility indicator, and the Pell Grant additional eligibility indicator; Pell Grant collection status indicator and overpayment collection information; promissory notes, Direct Loan Entrance Counseling forms, Federal Student Loan Exit Counseling forms, PLUS Loan Counseling forms, the Annual School Loan Acknowledgement (ASLA), Direct PLUS Loan Requests, endorser addendums, and counseling in the Direct Loan and TEACH Grant programs, such as the date that applicant completed counseling; PLUS Loan credit report information; applicant identifier information for an electronic request to repay a Direct Loan under an income-driven repayment plan and endorser/spouse information, such as the SSN, date that applicant completed the income-driven repayment plan application, and current loan balances; Electronic Direct Consolidation Loan borrower identifier information, such as the borrower's SSN, the date that borrower completed the Federal Direct Consolidation Loan application and promissory note, and current loan balances; and credit check decisions, credit appeals, credit appeal identifiers, and credit history information to support the credit appeal process. Further, information from the ''Enterprise Data Management and Analytics Platform Services (EDMAPS)'' (18–11–22) system of records is accessible in the DCC IT system to: allow real-time updates to a customer's identifiers, demographic attributes, address, phone, and email contact details; update customer preference for receiving marketing information via text message; allow the Department and its contractors to identify customers who have completed a customer satisfaction survey; and enable the Department to contact borrowers who have been identified by the Department as potentially having fraudulent activity from a Third-Party Debt Relief (TPDR) company and are at risk of loan default. The following information is modifiable by the customer through *StudentAid.gov:* name, DOB, address, phone number, and email address. The DCC IT system also sends the following

information to the EDMAPS system for analytics and reporting: case information including complaints, and OIG fraud referral data. Information includes, but is not limited to: SSN, DOB, address, phone, and email. Additionally, some information from Federal Loan Servicers' systems (covered by the ''Common Services for Borrowers (CSB)'' (18–11–16) system of records) is accessible on *StudentAid.gov* to allow customers to view their payment information, loan information, and to make payments on *StudentAid.gov* as they would on the various Federal Loan Servicer websites. Further, customers can use *StudentAid.gov* to update their contact information and access financial aid history that is stored in the ''National Student Loan Data System (NSLDS)'' (18–11–06) system of records. Additionally, until CPS is decommissioned after September 30, 2024, CPS is also used as a pass-through to send information that is stored in the ''Person Authentication Service (PAS)'' (18–11–12) system of records to SSA for computer matching on individuals who apply for an FSA ID in PAS in order to assist the Department in verifying their identities. The information includes, but is not limited to: SSN, name, and DOB. Finally, beginning with the 2024–25 award year application cycle, the IRS will disclose directly to the Department FTI for FAFSA application processing and aid eligibility determination; that FTI will not be maintained in this system. Beginning July 30, 2023, the IRS will also disclose directly to the Department FTI to determine eligibility and monthly payment amounts under Income-Driven Repayment (IDR) plans; that FTI also will not be maintained in this system. All FTI that the Department will obtain directly from the IRS under the FUTURE Act will be maintained within the FTI Module (FTIM) system that will be compliant with the IRS Publication 1075, ''Tax Information Security Guidelines for Federal, State and Local Agencies, Safeguards for Protecting Federal Tax Returns and Return Information,'' and that will be covered under the Department's system of records notice entitled ''FUTURE Act System (FAS)'' (18–11–23). This system will continue to maintain both historical income information (obtained from the IRS until CPS is decommissioned) and applicant-provided income information (either through a manual FAFSA entry or submission of alternative documentation of income (ADOI) through the IDR process). Any reference to income throughout this system of records notice refers explicitly to income information that the Department did not obtain directly from the IRS but obtained from the applicant or from another source.

RECORD SOURCE CATEGORIES:

Information maintained in this system of records is obtained from applicants, the parents of dependent applicants, third-party preparers, and the spouse of married applicants for title IV, HEA program assistance, on the paper FAFSA, Portable Document Format (PDF) FAFSA, the online FAFSA form, and FAFSA by phone; the authorized employees or representatives of authorized entities (namely, IHEs, institutional third-party servicers, FFEL Program lenders, FFEL Program guaranty agencies, Federal loan servicers, State grant agencies, other Federal agencies, and research agencies); and from other persons or entities from which information is obtained following a disclosure under the routine uses set forth below.

The Financial Aid Administrators at IHEs designated by the applicant and IHEs' third-party servicers may correct the records in this system as a result of documentation provided by the applicant or by a dependent applicant's parents, such as Federal income return(s) (IRS Form 1040), Social Security card(s), and Department of Homeland Security I–551 Permanent Resident Card.

This system maintains information added during CPS processing and that will be added during FPS processing and information received from other Department systems, including the NSLDS, the COD System, and the SAIG Participation Management System. The results of matching programs with Federal agencies or State or local governments, or agencies thereof, are added to the student's record during CPS processing and will be added to the student's record during FPS processing. The Department's matching programs at the time of the publication of this system of records notice are with the SSA to verify the SSNs of applicants, dependent applicants' parent(s), and spouses of married applicants, as well as of individuals who apply for an FSA ID, and to confirm the U.S. citizenship status of applicants as recorded in SSA records and date of death (if applicable) of applicants, and dependent applicants' parents, pursuant to title IV of the HEA, including sections 428B(f)(2), 483(a)(12) (which under the FAFSA Simplification Act will be section 483(a)(2)(B)), and 484(g) and (p) (which the FAFSA Simplification Act redesignates as section 484(o)) of the HEA (20 U.S.C. 1078–2(f)(2), 1090(a)(12) (which the FAFSA Simplification Act amends to be 1090(a)(2)(B)), and 1091(g) and (p) (which the FAFSA Simplification Act redesignates as 1091(o)); with the Department of Veterans Affairs (VA) to verify the status of applicants who claim to be veterans, pursuant to section 480(c) and (d)(1)(D) of the HEA (20 U.S.C. 1087vv(c) and (d)(1)(D)); with the U.S. Department of Homeland Security (DHS) to confirm the immigration status of applicants for assistance as authorized by section 484(g) of the HEA (20 U.S.C. 1091(g)); with the U.S. Department of Justice (DOJ) to enforce any requirement imposed at the discretion of a court, pursuant to section 5301 of the Anti-Drug Abuse Act of 1988, Public Law 100–690, as amended by section 1002(d) of the Crime Control Act of 1990, Public Law 101–647 (21 U.S.C. 862), denying Federal benefits under the programs established by title IV of the HEA to any individual convicted of a State or Federal offense for the distribution or possession of a controlled substance; and, through award year 2023–2024 following the implementation of the FAFSA Simplification Act on July 1, 2024, with the U.S. Department of Defense (DoD) to identify dependents of U.S. military personnel who died in service in Iraq and Afghanistan after September 11, 2001, to determine if they are eligible for increased amounts of title IV, HEA program assistance, pursuant to sections 420R and 473(b) of the HEA (20 U.S.C. 1070h and 1087mm(b)), which will be replaced by Section 401(c) under the FAFSA Simplification Act.

During CPS and FPS processing, the Department's COD System sends information to these systems for students who have received a Federal Pell Grant. CPS and FPS use this information for verification analysis and for end-of-year reporting. These data elements include, but are not limited to: Verification Selection and Status, Potential Over-award Project (POP) indicator, Institutional Cost of Attendance, Reporting and Attended Campus Pell ID and Enrollment Date, and Federal Pell Grant Program information (Scheduled Federal Pell Grant Award, Origination Award Amount, Total Accepted Disbursement Amount, Number of Disbursements Accepted, Percentage of Eligibility Used At This Attended Campus Institution, and Date of Last Activity from the Origination or Disbursement table).

CPS and FPS also receive applicant information from the Department's NSLDS system each time an application is processed or corrected. This process assesses student aid eligibility, updates

financial aid history, and ensures compliance with title IV, HEA regulations. Some of this information appears on the applicant's SAR and ISIR. Title IV, HEA award information is provided to NSLDS from several different sources. Federal Perkins Loan information and Federal Supplemental Educational Opportunity Grant (FSEOG) overpayment information is sent from IHEs or their third-party servicers; the Department's COD System provides Federal Pell Grant and Direct Loan data; and State and guaranty agencies provide information on FFEL loans received from lending institutions participating in the FFEL programs. Financial aid transcript information reported by NSLDS provides aid recipients, IHEs, and third-party servicers with information about the type(s), amount(s), dates, and overpayment status of prior and current title IV, HEA funds the aid recipient has received. FFEL and William D. Ford Federal Direct Student Loan data information reported by NSLDS includes, but is not limited to: (1) Aggregate Loan Data, such as Subsidized, Unsubsidized; Combined Outstanding Principal Balances; Unallocated Consolidated Outstanding Principal Balances, Subsidized, Unsubsidized; Combined Pending Disbursements, Subsidized, Unsubsidized; Combined Totals; and Unallocated Consolidated Totals; (2) Detailed Loan Data, such as Loan Sequence Number; Loan Type Code; Loan Change Flag; Loan Program Code; Current Status Code and Date; Outstanding Principal Balance and Date; Net Loan Amount; Loan Begin and End Dates; Amount and Date of Last Disbursement; Guaranty Agency Code; School Code; Contact Code; and Institution Type and Grade Level; and (3) system flags for Additional Unsubsidized Loan; Capitalized Interest; Defaulted Loan Change; Discharged Loan Change; Loan Satisfactory Repayment Change; Active Bankruptcy Change; Overpayments Change; Aggregate Loan Change; Defaulted Loan; Discharged Loan; Loan Satisfactory Repayment; Active Bankruptcy; Additional Loans; Direct Loan Master Promissory Note; Direct PLUS Loan Master Promissory Note; Subsidized Loan Limit; and the Combined Loan Limit. Federal Perkins Loan information reported by NSLDS includes, but is not limited to: Cumulative and Current Year Disbursement Amounts; flags for Perkins Loan Change; Defaulted Loan; Discharged Loan; Loan Satisfactory Repayment; Active Bankruptcy; Additional Loans; and Perkins Overpayment Flag and Contact (School or Region). Federal Pell Grant payment information reported includes, but is not limited to: Pell Sequence Number; Pell Attended School Code; Pell Transaction Number; Last Update Date; Scheduled Amount; Award Amount; Amount Paid to Date; Percent Scheduled Award Used; Pell Payment EFC; Flags for Pell Verification; and Pell Payment Change. TEACH Grant Program information includes, but is not limited to: TEACH Grant Overpayment Contact; TEACH Grant Overpayment Flag; TEACH Grant Loan Principal Balance; TEACH Grant Total; and TEACH Grant Change Flag. Iraq and Afghanistan Service Grants information includes, but is not limited to, Total Award Amount. The Department obtains from and exchanges information that is included in this system of records with IHEs, third-party servicers, and State agencies. These eligible entities register with the SAIG system to participate in the information exchanges specified for their business processes.

During FPS processing, this system will receive the SAI information from the Department's FAS. The SAI is calculated using FTI that the IRS will provide directly to the Department under the FUTURE Act that will not be maintained in this system, but instead the system of records entitled ''FUTURE Act System (FAS)'' (18–11–23).

Additionally, for individuals who request assistance from the Department, directly or through State requestors and legal assistance organizations (''third-party requestors''), as these terms are defined in 34 CFR 685.401(a), who may request that the Secretary of Education form a group of Federal student loan borrowers for borrower defense relief, information is obtained from individuals (*e.g.,* borrowers), their counsel or representatives, or students or their parents (when the individual is a borrower and depending on whether the individual is a parent or student), Federal agencies, State agencies, IHEs, lenders, private collection agencies, guaranty agencies, accreditors, and from other persons or entities from whom or from which data is obtained following a disclosure under routine uses set forth below.

Note: Some customer information that is retrieved from Federal Loan Servicers' IT systems (covered by the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16)) is accessible through StudentAid.gov to provide customers with payment and loan information and to enable customers to make loan payments as they would on the various Federal Loan Servicer websites. Information that is collected in this system is stored in and retrieved from the COD System (covered by the system of records notice entitled ''Common Origination and Disbursement (COD) System'' (18–11–02)) to allow: applicants and borrowers to submit Counseling (Entrance, Exit, Financial Awareness Counseling, PLUS, TEACH Grant Initial and Subsequent, TEACH Grant Exit, TEACH Grant Conversion), Master Promissory Note (MPN), Endorser Addendum, TEACH Grant Agreement to Serve or Repay (Agreement), Loan Consolidation, Income-Driven Repayment, PLUS Loan Request, and Annual Student Loan Acknowledgement (ASLA) applications through StudentAid.gov; credit check decision, credit appeal, and credit history information to be viewable on StudentAid.gov to support credit appeal processing; users to view and search the PSLF employer database as retrieved from the COD System and provide updates to employers' information; and the PDF version of the PSLF/Temporary Expanded PSLF (TEPSLF) certification and application form that is generated from the PSLF Help Tool to be accessible. Information is also retrieved from the COD System to provide StudentAid.gov functionality for creating and updating customer records. The following information from the EDMAPS system is accessible in the DCC IT system: customer information that is retrieved to allow real-time updates to a customer's identifiers, demographic attributes, address, phone, and email contact details; SMS opt-in/out information for customer communication preferences to opt-in/out of receiving marketing information via text message; information for customers who have been identified by the Department and its contractors as having completed a customer satisfaction survey; information for borrowers who will be contacted by the Department because they have been identified by the Department as having potentially fraudulent activity from a TPDR company; and information on borrowers who have been identified by the Department and its contractors as being at risk for loan default.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The Department may disclose information maintained in a record in this system of records under the routine uses listed in this system of records notice without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. These disclosures may be made on a case-by-

case basis or pursuant to a computer matching agreement that meets the requirements of the Privacy Act of 1974, as amended (Privacy Act) (5 U.S.C. 552a). Until June 30, 2024, Section 483(a)(3)(E) of the HEA (20 U.S.C. 1090(a)(3)(E)) restricts the use of the information gathered from the electronic version of the FAFSA to the application, award, and administration of aid awarded under title IV of the HEA, aid awarded by States, aid awarded by eligible institutions, or aid awarded by such entities as the Secretary of Education may designate.

(1) *Program Disclosures.* The Department may disclose records from the system of records for the following program purposes:

(a) To verify the identity of the applicant, the spouse of a married applicant, and the parent(s) of a dependent applicant, to verify, until CPS is decommissioned after September 30, 2024, the identities of individuals who apply for a FSA ID, to determine the accuracy of the information contained in the record, to support compliance with title IV, HEA statutory and regulatory requirements, and to assist with the determination, correction, processing, tracking, and reporting of program eligibility and benefits, the Department may disclose records to applicants, guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, local, or Tribal agencies;

(b) To provide an applicant's financial aid history to IHEs, guaranty agencies and State agencies, lenders and loan holders participating in the FFEL Program, and third-party servicers, including information about the applicant's title IV, HEA loan defaults, and title IV, HEA grant program overpayments, the Department may disclose records to IHEs, guaranty agencies and State agencies, lenders and loan holders participating in the FFEL Program, and third-party servicers;

(c) To facilitate receiving and correcting application information, processing Federal Pell Grants and Direct Loans, and reporting Federal Perkins Loan Program expenditures to the Department's processing and reporting systems, the Department may disclose records to IHEs, State agencies, and third-party servicers;

(d) To assist loan holders with the collection and servicing of title IV, HEA loans, to support pre-claims/supplemental pre-claims assistance, to assist in locating borrowers, and to assist in locating students who owe grant overpayments, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, local, and Tribal agencies;

(e) To facilitate assessments of title IV, HEA program compliance, the Department may disclose records to guaranty agencies and IHEs, third-party servicers, and Federal, State, and local agencies;

(f) To assist in locating holders of loans, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, and local agencies;

(g) To assist in assessing the administration of title IV, HEA program funds by guaranty agencies, lenders and loan holders in the FFEL Program, IHEs, and third-party servicers, the Department may disclose records to Federal and State agencies;

(h) To enforce the terms of a loan or grant or to assist in the collection of loan or grant overpayments, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, and local agencies;

(i) To assist borrowers in repayment, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, and local agencies;

(j) To determine the relief that is appropriate if the Secretary of Education grants a borrower defense to repayment discharge application, as well as to pursue the recovery of liabilities of such discharges against the IHE, the Department may disclose records to Federal, State, and Tribal agencies, accreditors, IHEs, lenders and loan holders, guaranty agencies, third-party servicers, and private collection agencies;

(k) To initiate legal action against an individual or entity involved in an illegal or unauthorized title IV, HEA program expenditure or activity, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, local, and Tribal agencies;

(l) To initiate or support a limitation, suspension, or termination action, an emergency action, or a debarment or suspension action, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, local, and Tribal agencies;

(m) To investigate and resolve complaints, inquiries, requests for assistance, requests for Federal student loan repayment relief and other relief under the borrower defense to repayment regulations, and to update borrower account records and to correct errors, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, accreditors, IHEs, third-party requestors, third-party servicers, private collection agencies, and Federal, State, and local agencies;

(n) To inform the parent(s) of a dependent applicant of information about the parent(s), or the spouse of a married applicant of information about the spouse, in an application for title IV, HEA funds, the Department may disclose records to the parent(s), or spouse, respectively;

(o) To identify the student as the correct beneficiary of the PLUS loan funds, and to allow the processing of the PLUS loan application and promissory note, the Department may disclose records to the parent(s) applying for the parent PLUS loan;

(p) To encourage a student to complete a FAFSA that they started but did not submit or to assist a student with the completion of a FAFSA, the Department may disclose an student's FAFSA filing status to a local educational agency, a secondary school where the student is or was enrolled, a State, local, or Tribal agency, or an entity that awards aid to students and that the Secretary of Education has designated under section 483(a)(3)(E) of the HEA (20 U.S.C. 1090(a)(3)(E)), prior to the amendments of the HEA made by the FAFSA Simplification Act (Pub. L. 116–260) and the FAFSA Simplification Technical Corrections Act (Pub. L. 117–103), which are effective July 1, 2024;

(q) Through June 30, 2024, the Department may disclose records from this system to State higher education agencies, eligible IHEs, and other entities that the Secretary of Education has designated under section 483(a)(3)(E) of the HEA (20 U.S.C. 1090(a)(3)(E)) that award and administer aid to students, to determine an applicant's eligibility for the award of aid by State higher education agencies, eligible IHEs, or by other entities the Secretary of Education has designated. (Beginning July 1, 2024, under amendments to the HEA made by the FAFSA Simplification Act and the FAFSA Simplification Technical Corrections Act, the Department will no longer rely on this authority to disclose records from this system to State higher education agencies, eligible IHEs, and other entities that the Secretary of

Education has designated under section 483(a)(3)(E) of the HEA (20 U.S.C. 1090(a)(3)(E)); and

(r) To help Federal, State, Tribal, and local government entities exercise their supervisory and administrative powers (including, but not limited to licensure, examination, discipline, regulation, or oversight of IHEs, Department contractors, guaranty agencies, lenders and loan holders, and third-party servicers) or to respond to aid applicant or recipient complaints submitted regarding the practices or processes of the Department and/or the Department's contractors, or to update information or correct errors contained in Department records regarding the aid applicant's or recipient's title IV, HEA program funds, the Department may disclose records to governmental entities at the Federal, State, Tribal, and local levels. These records may include all aspects of loans and grants made under title IV of the HEA to permit these governmental entities to verify compliance with applicable debt collection, consumer protection, financial, and other applicable statutory, regulatory, or local requirements. Before making a disclosure to these Federal, State, local, or Tribal governmental entities, the Department will require them to maintain safeguards consistent with the Privacy Act to protect the security and confidentiality of the disclosed records.

Note: Some information that is maintained in this system of records is also maintained in other Department systems of records and, therefore, may be disclosed pursuant to the routine uses published in those other systems' system of records notices, including the ''Common Origination and Disbursement (COD) System'' (18–11–02), ''National Student Loan Data System (NSLDS)'' (18–11–06), and ''Common Services for Borrowers (CSB)'' (18–11–16).

(2) *Enforcement Disclosure.* In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statute, regulations, or order of a competent authority, the Department may disclose the relevant records to the appropriate agency, whether Federal, State, Tribal, or local, charged with the responsibility of investigating or prosecuting that violation or charged with enforcing or implementing the statute, Executive Order, rule, regulation, or order issued pursuant thereto.

(3) *Litigation and Alternative Dispute Resolution (ADR) Disclosure.*

(a) *Introduction.* In the event that one of the parties listed in sub-paragraphs (i) through (v) of this routine use is involved in judicial or administrative litigation or ADR, or has an interest in judicial or administrative litigation or ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c), and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department or any of its components;

(ii) Any Department employee in their official capacity;

(iii) Any Department employee in their individual capacity where the U.S. Department of Justice (DOJ) agrees to or has been requested to provide or arrange for representation of the employee;

(iv) Any Department employee in their individual capacity where the Department has agreed to represent the employee; and

(v) The United States, where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) *Disclosure to the DOJ.* If the Department determines that disclosure of certain records to the DOJ is relevant and necessary to judicial or administrative litigation or ADR, the Department may disclose those records as a routine use to the DOJ.

(c) *Adjudicative Disclosure.* If the Department determines that it is relevant and necessary to judicial or administrative litigation or ADR to disclose certain records to an adjudicative body before which the Department is authorized to appear or to a person or entity designated by the Department or otherwise empowered to resolve or mediate disputes, the Department may disclose those records as a routine use to the adjudicative body, person, or entity.

(d) *Disclosure to Parties, Counsel, Representatives, and Witnesses.* If the Department determines that disclosure of certain records is relevant and necessary to judicial or administrative litigation or ADR, the Department may disclose those records as a routine use to the party, counsel, representative, or witness.

(4) *Freedom of Information Act (FOIA) and Privacy Act Advice Disclosure.* The Department may disclose records to the DOJ or to the Office of Management and Budget (OMB) if the Department determines that disclosure is desirable or necessary in determining whether records are required to be disclosed under the FOIA or the Privacy Act.

(5) *Contract Disclosure.* If the Department contracts with an entity to perform any function that requires disclosing records in this system of records to the contractor's employees, the Department may disclose the records to those employees. As part of such a contract, the Department shall require the contractor to agree to establish and maintain safeguards to protect the security and confidentiality of the disclosed records.

(6) *Congressional Member Disclosure.* The Department may disclose the records of an individual to a member of Congress or the member's staff when necessary to respond to an inquiry from the member made at the written request of and on behalf of the individual whose records are being disclosed. The member's right to the information is no greater than the right of the individual who requested it.

(7) *Employment, Benefit, and Contracting Disclosure.*

(a) *For Decisions by the Department.* The Department may disclose a record to a Federal, State, or local agency, or to another public agency or professional organization, maintaining civil, criminal, or other relevant enforcement or other pertinent records, if necessary to obtain information relevant to a Department decision concerning the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

(b) *For Decisions by Other Public Agencies and Professional Organizations.* The Department may disclose a record to a Federal, State, local, or other public agency or professional organization, or the Department's contractor in connection with the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit, to the extent that the record is relevant and necessary to the receiving entity's decision on the matter.

(8) *Employee Grievance, Complaint, or Conduct Disclosure.* If a record is relevant and necessary to an employee grievance, complaint, or disciplinary action involving a present or former employee of the Department, the Department may disclose a record from this system of records in the course of investigation, fact-finding, or adjudication to any party to the grievance, complaint, or action; to the party's counsel or representative; to a witness; or to a designated fact-finder, mediator, or other person designated to resolve issues or decide the matter.

(9) *Labor Organization Disclosure.* The Department may disclose records from this system of records to an

arbitrator to resolve disputes under a negotiated grievance procedure or to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation.

(10) *Disclosure to the DOJ.* The Department may disclose records to the DOJ to the extent necessary for obtaining DOJ advice on any matter relevant to an audit, inspection, or other inquiry related to the programs covered by this system.

(11) *Research Disclosure.* The Department may disclose records to a researcher if the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The Department may disclose records from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher must agree to establish and maintain safeguards to protect the security and confidentiality of the disclosed records.

(12) *Disclosure to the OMB and Congressional Budget Office (CBO) for Federal Credit Reform Act (FCRA) Support.* The Department may disclose records to OMB and CBO as necessary to fulfill FCRA requirements in accordance with 2 U.S.C. 661b.

(13) *Disclosure in the Course of Responding to Breach of Data.* The Department may disclose records to appropriate agencies, entities, and persons when (a) the Department suspects or has confirmed that there has been a breach of the system of records; (b) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(14) *Disclosure in Assisting another Agency in Responding to a Breach of Data.* The Department may disclose records from this system of records to another Federal agency or Federal entity, when the Department determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach, or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(15) *Disclosure of Information to State and Federal Agencies.* The Department may disclose records from this system of records to (a) a Federal or State agency, its employees, agents (including contractors of its agents), or contractors, or (b) a fiscal or financial agent designated by the U.S. Department of the Treasury, including employees, agents, or contractors of such agent, for the purpose of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds.

(16) *Disclosure to the National Archives and Records Administration (NARA).* The Department may disclose records from this system of records to NARA for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

(17) *Disclosure to Consumer Reporting Agencies:* Disclosures pursuant to 5 U.S.C. 552a(b)(12): The Department may disclose the following information to a consumer reporting agency regarding a valid, overdue claim of the Department: (a) the name, address, taxpayer identification number, and other information necessary to establish the identity of the individual responsible for the claim; (b) the amount, status, and history of the claim; and (c) the program under which the claim arose. The Department may disclose the information specified in this paragraph under 5 U.S.C. 552a(b)(12) and the procedures contained in subsection 31 U.S.C. 3711(e). A consumer reporting agency to which these disclosures may be made is defined at 15 U.S.C. 1681a(f) and 31 U.S.C. 3701(a)(3).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

System records are paper-based and stored in locked rooms or electronic and stored on secured computer systems and in the cloud.

Fully processed paper applications and supporting paper documentation that are received on or before June 30, 2024, are stored for applicable periods in standard Federal Records Center boxes in locked storage rooms at the contractor facilities in London, Kentucky. Fully processed paper applications and supporting paper documentation requiring retention and received on or after July 1, 2024, will be stored in a private records storage facility, as applicable. The records storage facilities currently utilized are listed in the ''System Location'' section above.

Digitized paper applicant records, which include optically imaged documents, are stored on DADS (disks) in a virtual disk library, which is also electronic, in the computer facilities controlled by the Next Generation Data Center (NGDC) in Clarksville, VA.

Records that are collected in this system for applicants of Federal grants or loans are stored in the COD System for individuals who apply under one of the programs authorized under title IV of the HEA, including, but not limited to the: (1) Federal Pell Grant Program; (2) Federal Perkins Loans Program; (3) ACG Program; (4) National SMART Grant Program; (5) TEACH Grant Program; (6) Iraq and Afghanistan Service Grant Program; (7) Direct Loan Program, which includes Federal Direct Stafford/Ford Loans, Federal Direct Unsubsidized Stafford/Ford Loans and Federal Direct PLUS Loans and Federal Direct Consolidation Loans; (8) FFEL Program; and (9) FISL Program.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records in this system pertaining to a title IV, HEA loan applicant, borrower, or grant recipient are indexed and retrieved by a single data element, or a combination of the following data elements, to include SSN, name, DOB, the award year in which the applicant applied for title IV, HEA program assistance, and case tracking number. These data elements are also used to retrieve information of title IV, HEA program applicants for and recipients of Federal grants or loans from the COD System (applicant information is collected in this system of records and stored in the COD System).

This system also uses a credit appeal identifier to retrieve credit appeal information from the COD System to support the credit appeal process.

Additionally, this system uses a combination of SSN, DOB, and name data elements to retrieve some records from Federal Loan Servicers' systems (covered by the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16)) to allow customers to access their payment information, loan information and to make payments on StudentAid.gov as they would on the various Federal Loan Servicer websites.

This system also uses customer identifiers to retrieve customer information data from the EDMAPS system (covered by the system of records noticed entitled ''Enterprise Data Management and Analytics

Platform Services (EDMAPS) System'' (18–11–22)) to allow real-time updates to customer information and communication preferences; and for the Department and its contractors to identify customers who have completed a customer satisfaction survey in the DCC system; who may have potential fraudulent activity from a TPDR company; and who may be at risk for loan default.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records maintained in this system are primarily retained and disposed of in accordance with the records schedules listed below. The Department has submitted amendments to these records schedules to NARA for its review and approval.

(a) Department Records Schedule 051: FSA National Student Loan Data System (NSLDS) (DAA–0441–2017–0004) (ED 051). (Records covered by ED 051 will not be destroyed until NARA-approved amendments to ED 051 are in effect, as applicable.)

(b) Department Records Schedule 052: Ombudsman Case Files (N1–441–09–21) (ED 052). (Records covered by ED 052 will not be destroyed until NARA-approved amendments to ED 052 are in effect, as applicable.)

(c) Department Records Schedule 072: FSA Application, Origination, and Disbursement Records (DAA–0441–2013–0002) (ED 072). (Records covered by ED 072 will not be destroyed until NARA-approved amendments to ED 072 are in effect, as applicable.)

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All users of the system will have a unique user ID with a password. All physical access to the data housed at system locations is controlled and monitored by security personnel who check each individual entering the building for their employee or visitor badge. The IT systems employed by the Department offers a high degree of resistance to tampering and circumvention with firewalls, encryption, and password protection. This security system limits data access to Department and contract staff on a ''need-to-know'' basis and controls individual users' ability to access and alter records within the system. All interactions by users of the system are recorded.

In accordance with the Federal Information Security Management Act of 2002 (FISMA), as amended by the Federal Information Security Modernization Act of 2014, every Department system must receive a signed Authorization to Operate (ATO) from a designated Department official. The ATO process includes a rigorous assessment of security and privacy controls, a plan of actions and milestones to remediate any identified deficiencies, and a continuous monitoring program.

FISMA controls implemented are comprised of a combination of management, operational, and technical controls, and include the following control families: access control, awareness and training, audit and accountability, security assessment and authorization, configuration management, contingency planning, identification and authentication, incident response, maintenance, media protection, physical and environmental protection, planning, personnel security, privacy, risk assessment, system and services acquisition, system and communications protection, system and information integrity, and program management.

RECORD ACCESS PROCEDURES:

If you wish to gain access to a record in this system, contact the respective system manager at the address listed above. You must provide necessary particulars such as your name, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name.

Alternatively, to gain access to a record in the system, you may make a Privacy Act request through the U.S. Department of Education, FOIA Service Center at *https://www2.ed.gov/policy/gen/leg/foia/request_privacy.html* by completing the applicable request forms. Requests by an individual for access to a record must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

Borrowers are able to access their financial aid history from NSLDS in this system. If you wish to gain access to other records in the NSLDS, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''National Student Loan Data System (NSLDS)'' (18–11–06).

For title IV, HEA program applicants and recipients of Federal grants or loans, if you wish to gain access to such information about you from the COD System, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''Common Origination and Disbursement (COD) System'' (18–11–02).

If you wish to gain access to the EDMAPS system information that is about you and accessible in this system, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''Enterprise Data Management and Analytics Platform Services (EDMAPS) System'' (18–11–22).

If you wish to gain access to the PAS system information about you that is maintained in this system until CPS is decommissioned after September 30, 2024, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''Person Authentication Service (PAS)'' (18–11–12).

If you wish to gain access to the information in the Federal Loan Servicers' IT systems that is about you and accessible in this system, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16).

CONTESTING RECORD PROCEDURES:

If you wish to contest or change the content of a record about you in the system of records, provide the respective system manager with your name, DOB, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name. Identify the specific items to be changed and provide a written justification for the change.

To contest information submitted or included on a FAFSA application for the current award year, send your request to the FOIA Service Center listed in the Notification Procedures section.

Financial aid history from NSLDS is accessible in this system. To contest name and address records about you, provide the respective system manager with your name, DOB, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name. All other financial aid history records from NSLDS must be contested by following the CONTESTING RECORD PROCEDURES identified in the system of records notice entitled ''National Student Loan Data System (NSLDS)'' (18–11–06).

For title IV, HEA program applicants and recipients of Federal grants or loans, if you wish to contest such information about you, please refer to the CONTESTING RECORD PROCEDURES section in the system of

records notice entitled ''Common Origination and Disbursement (COD) System'' (18–11–02).

To contest information about you in a Federal Loan Servicer IT system, such as the payment and loan information that is accessible in this system, please refer to the CONTESTING RECORD PROCEDURES section in the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16).

To contest the EDMAPS system information that is accessible in this system, please refer to the CONTESTING RECORD PROCEDURES section in the system of records notice entitled ''Enterprise Data Management and Analytics Platform Services (EDMAPS) System'' (18–11–22).

To contest the PAS system information about you that is maintained in this system until CPS is decommissioned after September 30, 2024, please refer to the CONTESTING RECORD PROCEDURES section in the system of records notice entitled ''Person Authentication Service (PAS)'' (18–11–12).

Requests to amend a record must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.7.

NOTIFICATION PROCEDURES:

If you wish to determine whether a record exists about you in the system of records, contact the respective system manager at the address listed above. You must provide necessary particulars such as your name, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name.

Alternatively, you may make a Privacy Act request through the U.S. Department of Education, FOIA Service Center at *https://www2.ed.gov/policy/gen/leg/foia/request_privacy.html* by completing the applicable request forms.

If you wish to submit a request for notification to determine whether a record exists about you in the COD System as a title IV, HEA program applicant or recipient of a Federal grant or loan, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''Common Origination and Disbursement (COD) System'' (18–11–02).

Borrowers are able to access their financial aid history from NSLDS in this system. If you wish to submit a request for notification to determine whether a record exists about you in the NSLDS system of records, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''National Student Loan Data System (NSLDS)'' (18–11–06).

If you wish to submit a request for notification to determine whether a record exists about you in a Federal Loan Servicer IT system, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16).

If you wish to submit a request for notification to determine whether a record exists about you in EDMAPS system, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''Enterprise Data Management and Analytics Platform Services (EDMAPS) System'' (18–11–22).

If you wish to submit a request for notification to determine whether a record exists about you in the PAS system, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''Person Authentication Service (PAS)'' (18–11–12).

Requests for notification about whether the system of records contains information about an individual must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The system of records entitled ''Aid Awareness and Application Processing'' (18–11–21) was originally published in full in the **Federal Register** on June 15, 2023 (88 FR 39233–39248).

[FR Doc. 2024–02135 Filed 1–31–24; 11:15 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 exempt wholesale generator filings:

Docket Numbers: EG24–95–000.
Applicants: Altona Solar, LLC.
Description: Altona Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 1/26/24.
Accession Number: 20240126–5220.
Comment Date: 5 p.m. ET 2/16/24.

Docket Numbers: EG24–96–000.
Applicants: BCD 2024 Fund 2 Lessee, LLC.
Description: BCD 2024 Fund 2 Lessee, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 1/26/24.
Accession Number: 20240126–5222.
Comment Date: 5 p.m. ET 2/16/24.

Docket Numbers: EG24–97–000.
Applicants: Serrano Solar, LLC.
Description: Serrano Solar, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 1/29/24.
Accession Number: 20240129–5164.
Comment Date: 5 p.m. ET 2/20/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1346–009.
Applicants: Frederickson Power L.P.
Description: Notice of Non-Material Change in Status of Frederickson Power L.P.
Filed Date: 1/25/24.
Accession Number: 20240125–5208.
Comment Date: 5 p.m. ET 2/15/24.

Docket Numbers: ER10–2502–012; ER10–2472–010; ER10–2473–011; ER11–2724–011; ER11–4436–010; ER18–2518–006; ER19–645–005.
Applicants: Black Hills Colorado Wind, LLC, Black Hills Electric Generation, LLC, Black Hills Power, Inc., Black Hills Colorado IPP, LLC, Cheyenne Light, Fuel and Power Company, Black Hills Wyoming, LLC, Black Hills Colorado Electric, LLC.
Description: Notice of Non-Material Change in Status of Black Hills Colorado Electric, LLC, et al.
Filed Date: 1/26/24.
Accession Number: 20240126–5233.
Comment Date: 5 p.m. ET 2/16/24.

Docket Numbers: ER11–2534–011.
Applicants: Morris Cogeneration, LLC.
Description: Notice of Non-Material Change in Status of Morris Cogeneration, LLC.
Filed Date: 1/29/24.
Accession Number: 20240129–5150.
Comment Date: 5 p.m. ET 2/20/24.

Docket Numbers: ER11–2539–008; ER11–2540–008; ER11–2542–008.
Applicants: Rathdrum Power, LLC, Plains End II, LLC, Plains End, LLC.
Description: Notice of Change in Status of Plains End, LLC, et al.
Filed Date: 1/29/24.
Accession Number: 20240129–5155.
Comment Date: 5 p.m. ET 2/20/24.

Docket Numbers: ER11–2765–007; ER12–2310–009.
Applicants: Zephyr Wind, LLC, Elk Wind Energy LLC.
Description: Notice of Non-Material Change in Status of Elk Wind Energy LLC, et al.

Filed Date: 1/26/24.
Accession Number: 20240126–5226.
Comment Date: 5 p.m. ET 2/16/24.
Docket Numbers: ER12–2676–002.
Applicants: Piedmont Green Power, LLC.
Description: Notice of Non-Material Change in Status of Piedmont Green Power, LLC.
Filed Date: 1/25/24.
Accession Number: 20240125–5209.
Comment Date: 5 p.m. ET 2/15/24.
Docket Numbers: ER17–2341–010; ER15–1218–015; ER15–2224–006; ER16–38–013; ER16–39–012; ER17–157–007; ER17–2453–009; ER18–713–008; ER18–1775–006; ER23–2294–001.
Applicants: Vikings Energy Farm LLC, 64KT 8me LLC, CA Flats Solar 150, LLC, Imperial Valley Solar 3, LLC, Moapa Southern Paiute Solar, LLC, Kingbird Solar B, LLC, Kingbird Solar A, LLC, Solar Star Colorado III, LLC, Solar Star California XIII, LLC, CA Flats Solar 130, LLC.
Description: Notice of Non-Material Change in Status of CA Flats Solar 130, LLC, et al.
Filed Date: 1/29/24.
Accession Number: 20240129–5144.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER20–242–005; ER20–245–005; ER20–246–005.
Applicants: Windhub Solar A, LLC, Sun Streams, LLC, Sunshine Valley Solar, LLC.
Description: Notice of Change in Status of Sunshine Valley Solar, LLC, et al.
Filed Date: 1/26/24.
Accession Number: 20240126–5224.
Comment Date: 5 p.m. ET 2/16/24.
Docket Numbers: ER20–391–009; ER21–2557–004; ER22–2662–004; ER22–2663–004; ER22–2664–004; ER23–1275–002; ER23–1276–002; ER23–1277–002.
Applicants: Aron Energy Prepay 23 LLC, Aron Energy Prepay 22 LLC, Aron Energy Prepay 21 LLC, Aron Energy Prepay 16 LLC, Aron Energy Prepay 15 LLC, Aron Energy Prepay 14 LLC, Aron Energy Prepay 5 LLC, J. Aron & Company LLC.
Description: Notice of Non-Material Change in Status of J. Aron & Company LLC, et al.
Filed Date: 1/26/24.
Accession Number: 20240126–5223.
Comment Date: 5 p.m. ET 2/16/24.
Docket Numbers: ER23–1582–001; ER23–2432–001.
Applicants: Misenheimer Solar LLC, Crooked Lake Solar, LLC.
Description: Notice of Non-Material Change in Status of Crooked Lake Solar, LLC, et al.
Filed Date: 1/25/24.
Accession Number: 20240125–5207.
Comment Date: 5 p.m. ET 2/15/24.
Docket Numbers: ER23–2812–002.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Amendment to Filing, Original ISA, SA No. 7065 to be effective 8/11/2023.
Filed Date: 1/26/24.
Accession Number: 20240126–5167.
Comment Date: 5 p.m. ET 2/16/24.
Docket Numbers: ER24–100–001.
Applicants: Adams Solar LLC.
Description: Notice of Non-Material Change in Status of Adams Solar LLC.
Filed Date: 1/29/24.
Accession Number: 20240129–5149.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER24–1026–000.
Applicants: Pixelle Androscoggin LLC.
Description: Notice of Cancellation of Market Based Rate Tariff of Pixelle Androscoggin LLC.
Filed Date: 1/25/24.
Accession Number: 20240125–5211.
Comment Date: 5 p.m. ET 2/15/24.
Docket Numbers: ER24–1027–000.
Applicants: Pixelle Energy Services LLC.
Description: Notice of Cancellation of Market Based Rate Tariff of Pixelle Energy Services LLC.
Filed Date: 1/25/24.
Accession Number: 20240125–5212.
Comment Date: 5 p.m. ET 2/15/24.
Docket Numbers: ER24–1028–000.
Applicants: Southwest Power Pool, Inc.
Description: Notice of Cancellation of Generator Interconnection Agreement of Southwest Power Pool, Inc.
Filed Date: 1/29/24.
Accession Number: 20240129–5031.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER24–1029–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2024–01–29_Schedule 31 Annual Update Filing to be effective 4/1/2024.
Filed Date: 1/29/24.
Accession Number: 20240129–5051.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER24–1030–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Service Agreement No. 406—Amendment No. 3 to be effective 3/30/2024.
Filed Date: 1/29/24.
Accession Number: 20240129–5055.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER24–1031–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3929 Twelvemile Energy Surplus Interconnection GIA Cancel to be effective 1/7/2024.
Filed Date: 1/29/24.
Accession Number: 20240129–5065.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER24–1033–000.
Applicants: FirstEnergy Pennsylvania Electric Company, PJM Interconnection, L.L.C.
Description: Tariff Amendment: FirstEnergy Pennsylvania Electric Company submits tariff filing per 35.15: FE PA submits Cancellation of IAs, SA Nos. 5327, 6623 and 6635 re: FE Reorg to be effective 1/1/2024.
Filed Date: 1/29/24.
Accession Number: 20240129–5089.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER24–1034–000.
Applicants: FirstEnergy Pennsylvania Electric Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: FirstEnergy Pennsylvania Electric Company submits tariff filing per 35.13(a)(2)(iii: FE PA submits Amended IA, SA No. 4161 re: FirstEnergy Reorganization to be effective 1/1/2024.
Filed Date: 1/29/24.
Accession Number: 20240129–5120.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER24–1035–000.
Applicants: 20SD 8me LLC.
Description: Baseline eTariff Filing: 20SD 8me LLC MBR Tariff to be effective 2/1/2024.
Filed Date: 1/29/24.
Accession Number: 20240129–5124.
Comment Date: 5 p.m. ET 2/20/24.
Docket Numbers: ER24–1038–000.
Applicants: FirstEnergy Pennsylvania Electric Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: FirstEnergy Pennsylvania Electric Company submits tariff filing per 35.13(a)(2)(iii: FE PA submits Amended IA, SA No. 4337 re: FirstEnergy Reorganization to be effective 1/1/2024.
Filed Date: 1/29/24.
Accession Number: 20240129–5158.
Comment Date: 5 p.m. ET 2/20/24.

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

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is

necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: January 29, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–02102 Filed 2–1–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6440–010]

Lakeport Hydroelectric One, LLC and New Hampshire Department of Environmental Services; Notice of Intent To Prepare an Environmental Assessment

On August 30, 2021, Lakeport Hydroelectric One, LLC (Lakeport) and New Hampshire Department of Environmental Services (New Hampshire DES) filed a relicense application for the 600-kilowatt Lakeport Hydroelectric Project No. 6440 (project). The project is located on the Winnipesaukee River in Laconia, Belknap County, New Hampshire.

In accordance with the Commission's regulations, on November 14, 2023, 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.

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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

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.	August 2024.[1]
Comments on EA	September 2024.

Questions regarding this notice may be directed to Erin Kimsey at (202) 502–8621 or *erin.kimsey@ferc.gov.*

Dated: January 29, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–02100 Filed 2–1–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP24–343–000.
Applicants: Big Sandy Pipeline, LLC.
Description: Compliance filing: Big Sandy Fuel Filing Effective 3–1–2024 to be effective N/A.
Filed Date: 1/26/24.
Accession Number: 20240126–5115.
Comment Date: 5 p.m. ET 2/7/24.

Docket Numbers: RP24–344–000.
Applicants: Columbia Gas Transmission, LLC.
Description: Compliance filing: VEP Incremental Rate Implementation CP21–498 to be effective 2/1/2024.
Filed Date: 1/26/24.
Accession Number: 20240126–5168.
Comment Date: 5 p.m. ET 2/7/24.

Docket Numbers: RP24–345–000.
Applicants: Guardian Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Combined Update to Non-Conforming and Negotiated Rate Agreements—January 2024 to be effective 2/26/2024.
Filed Date: 1/26/24.
Accession Number: 20240126–5170.
Comment Date: 5 p.m. ET 2/7/24.

Docket Numbers: RP24–346–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Negotiated Rates—Various Feb 1 2024 Releases to be effective 12/1/2023.
Filed Date: 1/29/24.
Accession Number: 20240129–5022.
Comment Date: 5 p.m. ET 2/12/24.

Docket Numbers: RP24–347–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Yankee Gas to Emera Energy eff 1–27–24 to be effective 1/27/2024.
Filed Date: 1/29/24.
Accession Number: 20240129–5032.
Comment Date: 5 p.m. ET 2/12/24.

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 p.m. eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available

[1] The Council on Environmental Quality's (CEQ) regulations under 40 CFR 1501.10(b)(1) require that EAs be completed within 1 year of the federal action agency's decision to prepare an EA. This notice establishes the Commission's intent to prepare an EA for the Lakeport Hydroelectric Project. Therefore, in accordance with CEQ's regulations, the EA must be issued within 1 year of the issuance date of this notice.

information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: January 29, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–02101 Filed 2–1–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7242–060]

STS Hydropower, LLC; Notice of Intent To Prepare an Environmental Assessment

On September 30, 2022, and supplemented on February 28 and April 28, 2023, STS Hydropower, LLC (licensee) filed an application to surrender its license for the Kanaka Hydroelectric Project No. 7242. The project is located on Sucker Run Creek, in Butte County, California. The project does not occupy any federal lands.

The project has been inoperable since August 2017 when the powerhouse, transmission lines, and electrical equipment were severely damaged or destroyed by the Ponderosa Wildfire. Considering the extensive damage to these project features, the licensee determined that it is not cost effective to restore project operation. Instead, the licensee proposes to surrender the license and remove most project features. The privately owned project dam would remain in place. A Notice of Application Accepted for Filing and Soliciting Comments, Motions to Intervene, and Protest was issued on March 23, 2023. On April 24, 2023, the California State Water Resources Control Board filed a timely motion to intervene. No additional comments were received in response to the Commission's notice.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the review of the proposed action. The planned schedule for the completion of the EA is June 2024.[1] Revisions to the schedule may be made as appropriate. The EA will be issued and made available for review by all interested parties. All comments filed on the EA will be reviewed by staff and considered in the Commission's final decision on the proceeding.

With this notice, the Commission is inviting federal, state, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal to cooperate in the preparation of the EA planned to be issued June 2024. Agencies wishing to cooperate, or further discuss the benefits, responsibilities, and obligations of the cooperating agency role, should contact staff listed at the bottom of this notice by February 19, 2024. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others to access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Any questions regarding this notice may be directed to Diana Shannon at 202–502–6136 or *diana.shannon@ferc.gov.*

Dated: January 29, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–02099 Filed 2–1–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 7630–005]

Town of South Hill, Virginia; Notice of Intent To Prepare an Environmental Assessment

On April 20, 2020, the Town of South Hill, Virginia (exemptee) filed an application to surrender its exemption from licensing for the Whittles Mill Dam Hydroelectric Project No. 7630. The project is located on the Meherrin River in the Town of South Hill in Mecklenburg County, Virginia. The project does not occupy Federal lands.

The exemptee proposes to surrender its exemption from licensing for the project. The project has been disconnected from its power source and has not operated since May 16, 2014. No ground disturbing activities are proposed and project features would remain in place, as they are part of the Whittle's Mill Historic Site and Park. A Notice of Application Accepted for Filing and Soliciting Comments, Motions to Intervene, and Protest was issued on June 3, 2020.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the proposed action. The planned schedule for the completion of the EA is June 2024.[1] Revisions to the schedule may be made as appropriate. The EA will be issued and made available for review by all interested parties. All comments filed on the EA will be reviewed by staff and considered in the Commission's final decision on the proceeding.

With this notice, the Commission is inviting Federal, State, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal to cooperate in the preparation of the EA planned to be issued June 2024. Agencies wishing to cooperate, or further discuss the benefits, responsibilities, and obligations of the cooperating agency role, should contact staff listed at the bottom of this notice by February 19, 2024. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others to access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Any questions regarding this notice may be directed to Rebecca Martin at 202–502–6012 or *Rebecca.martin@ferc.gov.*

Dated: January 29, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–02098 Filed 2–1–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 42 U.S.C. 4336a(g)(1)(B) requires lead federal agencies to complete EAs within 1 year of the agency's decision to prepare an EA.

[1] 42 U.S.C. 4336a(g)(1)(B) requires lead Federal agencies to complete EAs within 1 year of the agency's decision to prepare an EA.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1121–136]

Pacific Gas & Electric Company; Notice of Intent To Prepare an Environmental Assessment

On October 28, 2022, as supplemented on October 2, 2023, and December 1, 2023, Pacific Gas & Electric Company (PG&E or licensee) filed an application for a non-capacity amendment for the Battle Creek Hydroelectric Project No. 1121. The project is located on the mainstem Battle Creek, and on the North Fork and South Fork Battle Creek in Shasta and Tehama Counties, California. The project occupies Federal lands administered by the U.S. Forest Service and the Bureau of Land Management.

PG&E is requesting that its license for the Battle Creek Hydroelectric Project be amended to remove Inskip Diversion Dam, adjacent infrastructure, fish ladder, and approximately 30,000 to 56,000 cubic yards of sediment from behind the dam. No changes to long-term operations of the project are proposed. Inskip Diversion Dam would be removed and the inlet into Inskip Canal from Inskip Diversion Dam would be plugged. Once stored sediment is dredged and the dam is removed, the stream channel would be restored to a natural condition. A Notice of Application Accepted for Filing and Soliciting Comments, Motions to Intervene, and Protest was issued on December 29, 2022.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the proposed action. The planned schedule for the completion of the EA is May 2024.[1] Revisions to the schedule may be made as appropriate. The EA will be issued and made available for review by all interested parties. All comments filed on the EA will be reviewed by staff and considered in the Commission's final decision on the proceeding.

With this notice, the Commission is inviting Federal, State, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal to cooperate in the preparation of the EA planned to be issued May 2024. Agencies wishing to cooperate, or further discuss the benefits, responsibilities, and obligations of the cooperating agency role, should contact staff listed at the bottom of this notice by February 19, 2024. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. *See* 94 FERC ¶ 61,076 (2001).

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others to access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Any questions regarding this notice may be directed to Rebecca Martin at 202–502–6012 or *Rebecca.martin@ferc.gov.*

Dated: January 29, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–02103 Filed 2–1–24; 8:45 am]

BILLING CODE 6717–01–P

[1] 42 U.S.C. 4336a(g)(1)(B) requires lead Federal agencies to complete EAs within 1 year of the agency's decision to prepare an EA.

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11697–01–OW]

Notice of Public Listening Session of the Environmental Financial Advisory Board (EFAB) Water Affordability Workgroup

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public listening session.

SUMMARY: The Environmental Protection Agency (EPA) announces a public listening session via a webcast of the Environmental Financial Advisory Board (EFAB) Water Affordability Workgroup. The listening session will be held in real-time via webcast and public comments may be provided in writing in advance. Please see **SUPPLEMENTARY INFORMATION** for further details. The purpose of the listening session will be for the EFAB to solicit public comment on research, data, and case examples that demonstrate approaches to reduce the capital intensity of meeting communities' water and wastewater service needs. These could include technological innovations that reduce the required scale of capital projects, innovative procurement models that reduce overall capital costs, or policy innovations that enable communities to meet regulatory requirements more efficiently. The listening session will be conducted fully virtual via webcast.

DATES: The listening session will be held on February 20, 2024, from 1 p.m. to 3 p.m. eastern.

ADDRESSES:

Webcast: Information to access the webcast will be provided upon registration in advance of the listening session.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wants information about the listening session may contact Tara Johnson via telephone/voicemail at (202) 564–6186 or email to *efab@epa.gov.* General information concerning the EFAB is available at *www.epa.gov/waterfinancecenter/efab.*

SUPPLEMENTARY INFORMATION:

Background: The EFAB is an EPA advisory committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2, to provide advice and recommendations to EPA on innovative approaches to funding environmental programs, projects, and activities. Administrative support for the EFAB is provided by the Water Infrastructure and Resiliency Finance Center within EPA's Office of Water. Pursuant to FACA and EPA policy, notice is hereby given that the EFAB will hold a public listening session via a webcast to solicit public comment on research, data, and case examples that demonstrate approaches to reduce the capital intensity of meeting communities' water and wastewater service needs. These could include technological innovations that reduce the required scale of capital projects, innovative procurement models that reduce overall capital costs, or policy innovations that enable communities to meet regulatory requirements more efficiently.

Registration for the Listening Session: To register for the listening session, please visit *www.epa.gov/waterfinancecenter/efab#meeting.* Interested persons who wish to attend the listening session must register by February 18, 2024, to attend via webcast. Pre-registration is strongly encouraged. In the event the listening session cannot be held, an announcement will be made on the EFAB website at *www.epa.gov/waterfinancecenter/efab* and all registered attendees will be notified.

Availability of Listening Session Materials: Listening session materials, including the agenda and briefing

materials, will be available on EPA's website at *www.epa.gov/waterfinancecenter/efab.*

Procedures for Providing Public Input: Public comment for consideration by EPA's Federal advisory committees has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a Federal advisory committee is different from the process used to submit comments to an EPA program office. Federal advisory committees provide independent advice to EPA. Members of the public may submit comments on matters being considered by the EFAB for consideration as the Board develops its advice and recommendations to EPA.

Oral Statements: In general, individuals or groups requesting an oral presentation at a public listening session will be limited to three minutes each. Persons interested in providing oral statements at the February 2024 listening session should register in advance and provide notification, as noted in the registration confirmation, by February 13, 2024, to be placed on the list of registered speakers. Those providing oral statements may also submit supplementary written statements per the instructions below.

Written Statements: Written statements should be received by February 13, 2024, so that the information can be made available to the EFAB for its consideration prior to the listening session. Written statements should be sent via email to *efab@epa.gov.* Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the EFAB website. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities or to request accommodations for a disability, please register for the listening session and list any special requirements or accommodations needed on the registration form at least 10 business days prior to the listening session to allow as much time as possible to process your request.

Andrew D. Sawyers,

Director, Office of Wastewater Management, Office of Water.

[FR Doc. 2024–02089 Filed 2–1–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–108]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed January 22, 2024 10 a.m. EST Through January 29, 2024 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice: Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

EIS No. 20240014, Draft, FTA, NY, Port Authority Bus Terminal Replacement Project, *Comment Period Ends:* 03/18/2024, *Contact:* Ky Woltering 212–668–2558.

EIS No. 20240015, Final Supplement, USFS, AK, Greens Creek North Extension Project, *Review Period Ends:* 03/18/2024, *Contact:* Matthew Reece 907–586–7876.

Dated: January 29, 2024.

Julie Smith,

Acting Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2024–02118 Filed 2–1–24; 8:45 am]

BILLING CODE 6560–50–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 regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than March 4, 2024.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60604–1413. Comments can also be submitted electronically to *comments.applications@chi.frb.org:*

1. *Pluto Holdings Investments Inc., Tortola, British Virgin Islands;* to become a bank holding company by acquiring Ambanc Financial Services, Inc., and thereby indirectly acquiring American Bank of Beaver Dam, both of Beaver Dam, Wisconsin.

B. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be submitted electronically to *comments.applications@stls.frb.org:*

1. *Lincoln County Bancorp, Inc., Troy, Missouri;* to acquire additional voting shares of Kahoka State Bank, Kahoka, Missouri.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–02143 Filed 2–1–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10185]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect

information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by April 2, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10185 Medicare Part D Reporting Requirements

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''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 requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements; *Use:* Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at 42 CFR 423.514(a).

Data collected via the Medicare Part D reporting requirements will be an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections (Enrollment and Disenrollment, Medication Therapy Management (MTM) Programs, Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, and Employer/Union Sponsored Sponsors, and Medicare Prescription Payment Plan), data are reported electronically to CMS. The data collected via the MTM and Grievances reporting sections are used in the Medicare Part C and D Star Ratings and Display Measures. The other reporting sections' data are analyzed for program oversight to ensure the availability, accessibility, and acceptability of sponsors' services, such as coverage determinations and appeals processes, and opioid safety edits at the time of dispensing. *Form Number:* CMS–10185 (OMB Control Number: 0938–0992); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 1,019; *Number of Responses:* 14,325; *Total Annual Hours:* 19,900. (For policy questions regarding this collection contact Abigale Sanft at 410–786–6068.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–02095 Filed 2–1–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Survey of Staff Recruitment, Training, and Professional Development in Early Head Start (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children & Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to conduct a nationally representative survey of Early Head Start (EHS) grant recipients regarding their recruitment, hiring, and professional development practices.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* Identify all

requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The *Survey of Staff Recruitment, Training, and Professional Development in EHS* is a nationally representative survey that will describe how EHS programs ensure staff have the qualifications and competencies to deliver high-quality services to infants, toddlers, and their families. The information collection will examine how EHS grant recipients search for and hire qualified teaching and home visiting staff and support staff in their ongoing professional development and career advancement. The information collection aims to identify successful strategies or approaches as well as challenges faced as EHS programs search for, hire, and train teaching and home visiting staff. Findings are intended to inform program planning, training and technical assistance, and research.

Respondents: Early Head Start program directors or their designee.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
Survey instrument for center-based programs only	232	1	.5	116
Survey instrument for home-based programs only	56	1	.5	28
Survey instrument for programs with center-based and home-based options	312	1	.5	156

Estimated Total Annual Burden Hours: 300.

Authority: Head Start Act Section 640 [42 U.S.C. 9835].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–02061 Filed 2–1–24; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines Meeting; Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: HRSA published a notice in the **Federal Register** on October 12, 2023, concerning the 2024 calendar year meetings of the Advisory Commission on Childhood Vaccines (ACCV). The meeting times have changed. The 2024 ACCV meetings will be held from 1 p.m. eastern time (ET)–4 p.m. ET instead of from 10 a.m.–4 p.m.

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 8W–25A, Rockville, Maryland 20857; 800–338–2382; or *ACCV@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 12, 2023, FR Doc. 2023–22584, page 70680, column 2, correct the Dates caption to read: ''The ACCV meetings will be held on:

- March 7, 2024, 1 p.m. ET–4 p.m. ET;
- March 8, 2023, 1 p.m. ET–4 p.m. ET;
- September 5, 2023, 1 p.m. ET–4 p.m. ET;
- September 6, 2023, 1 p.m. ET–4 p.m. ET.''

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–02106 Filed 2–1–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request: Home Visiting Assessment of Implementation Quality Study: Understanding Supervisor Supports in Home Visiting

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 2, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Home Visiting Assessment of Implementation Quality Study: Understanding Supervisor Supports in Home Visiting, OMB No. 0915–xxxx—[NEW].

Abstract: The Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program, authorized by Social Security Act, title V, section 511 (42 U.S.C. 711) and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and for parents with young children up to kindergarten entry. States, tribal entities, and certain nonprofit organizations are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. Funding recipients may subaward grant funds to local implementing agencies (LIAs) to

provide home visiting services to eligible families in at-risk communities.

Through the Home Visiting Assessment of Implementation Quality study, HRSA aims to examine specific components of the Home Visiting Implementation Quality Conceptual Framework to inform strategies for implementing high quality home visiting programs. One of the three quality components the study will focus on is support for supervisors of home visitors. A qualified, stable, and supported home visitor workforce is an important quality component of home visiting, and supervision is a key part of supporting that workforce. The requested information collection will explore how training for supervisors may be linked to home visitor job satisfaction. It will also examine how supervisor training in important content areas (*e.g.,* substance use, intimate partner violence) may affect the extent to which home visitors talk to families about these topics. Data collection will include an online recruitment survey, interviews, and focus groups.

Need and Proposed Use of the Information: HRSA is seeking additional information about how the MIECHV Program can train and support supervisors of home visitors to provide high-quality supervision. HRSA intends to use this information to identify practices that MIECHV awardees and LIAs could use to best support home visiting supervisors, improving home visitors' ability to deliver high-quality home visiting services.

Likely Respondents: MIECHV-funded LIA staff, including program directors, coordinators, supervisors, and home visitors.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Recruitment Survey	250	1	250	0.17	42.5
LIA Program Director Interview Guide	50	1	50	1.00	50.0
Supervisor Focus Group Protocol	50	1	50	1.50	75.0
Home Visitor Focus Group Protocol	50	1	50	1.50	75.0
Total	400		400		242.5

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–02096 Filed 2–1–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Autoimmunity, Immunology and Transplantation.

Date: February 28, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Shannon J. Sherman, Ph.D., Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–0715, *shannon.sherman@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Advancing Therapeutics.

Date: February 28–29, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

Contact Person: Lystranne Alysia Maynard Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–4809, *lystranne.maynard-smith@nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Healthcare and Health Disparities Study Section.

Date: February 28–29, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Tara Roshell Earl, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1007C, Bethesda, MD 20892, (301) 402–6857, *earltr@mail.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Modeling and Analysis of Biological Systems Study Section.

Date: February 29–March 1, 2024.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: North Bethesda Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Zarana Patel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–9295, *zarana.patel@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology, Developmental Biology, and Bioengineering.

Date: February 29–March 1, 2024.

Time: 8:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Mufeng Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–5653, *limuf@nih.gov.*

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Cellular and Molecular Immunology—B Study Section.

Date: February 29–March 1, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Liying Guo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, (301) 827–7728, *lguo@mail.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Organization and Delivery of Health Services Study Section.

Date: February 29–March 1, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Catherine Hadeler Maulsby, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1266, *maulsbych@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience, and Vision.

Date: February 29–March 1, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Jennifer Kielczewski, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1042, *jennifer.kielczewski@nih.gov.*

Name of Committee: Applied Immunology and Disease Control Integrated Review Group; Vaccines Against Infectious Diseases Study Section.

Date: February 29–March 1, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Jian Wang, Ph.D., MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, MSC 7812, Bethesda, MD 20892, (301) 213–9853, *wangjia@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Therapeutic Immune Regulation Study Section.

Date: February 29–March 1, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Yue Wu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 803C, Bethesda, MD 20892, (301) 867–5309, *wuy25@csr.nih.gov.*

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Etiology, Diagnostic, Intervention and Treatment of Infectious Diseases Study Section.

Date: February 29–March 1, 2024.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, (301) 996–5819, *zhengli@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Maximizing Investigators' Research Award C Study Section.

Date: February 29–March 1, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–8559, *jimok.kim@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Genes, Genomes and Genetics.

Date: February 29–March 1, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Linda Wagner Jurata, Scientific Review Officer, The Center for Scientific Review, The National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–8032, *linda.jurata@nih.gov.*

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Innate Immunity and Inflammation Study Section.

Date: February 29–March 1, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Bakary Drammeh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 805–P, Bethesda, MD 20892, (301) 435–0000, *drammehbs@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02047 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Interventions to Address HIV-Related Comorbidities among

Highly Affected Populations Experiencing Health Disparities.

Date: March 21, 2024.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIMHD DEM II, Suite 800, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ivan K. Navarro, Ph.D., Scientific Review Officer, Office of Extramural Research Administration, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, 301–827–2061, *ivan.navarro@nih.gov.*

Dated: January 30, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02087 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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: National Institute on Aging Special Emphasis Panel; AD/ADRD Research—Renewal and Competing Revision Cooperative Agreements.

Date: February 29, 2024.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sandhya Sanghi, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2N230, (301) 496–2879, *sandhya.sanghi@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 30, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02122 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; 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: National Center for Complementary and Integrative Health Special Emphasis Panel; Clinical and Data Coordinating Center Applications for NCCIH Multi-Site Clinical Trials of Mind and Body Interventions.

Date: March 1, 2024.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, National Center for Complementary and Integrative Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual).

Contact Person: Baila S. Hall, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 443–9285, *baila.hall@nih.gov*.

Marta V. Hamity, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, *marta.hamity@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: January 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02050 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Precision Mental Health: Develop Tools to Inform Treatment Selection in Depression (UG3/UH3).

Date: February 29, 2024.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Neuroscience Center, Bethesda, MD 20892, (301) 435–1260, *jasenka.borzan@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; AMP SCZ: Clinical High Risk for Psychosis Clinical Trial Network and DPACC (U01 & U24).

Date: February 29, 2024.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN K99.

Date: March 6, 2024.

Time: 11:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: EMMA Perez-Costas, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20892, (240) 936–6720, *emma.perez-costas@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02045 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

Date: February 22–23, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jordan M. Moore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1002A1, Bethesda, MD 20892, (301) 451–0293, *jordan.moore@nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Technology Development Study Section.

Date: February 22–23, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, (301) 237–9870, *xuguofen@csr.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Host Interactions Study Section.

Date: February 22–23, 2024.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Angela Y. Ng, Ph.D., MBA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 710–C, MSC 7806, Bethesda, MD 20892, (301) 435–1715, *nga@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroscience of Interoception and Chemosensation Study Section.

Date: February 22–23, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Myongsoo Matthew Oh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1011F, Bethesda, MD 20892, (301) 435–1042, *ohmm@csr.nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review Group; Radiation Therapeutics and Biology Study Section.

Date: February 26–27, 2024.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–996–6208, *hongb@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Addiction Risks and Mechanisms Study Section.

Date: February 26–27, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Darcy Hotel, 1515 Rhode Island Ave. NW, Washington, DC 20005.

Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, (301) 496–0726, *prenticekj@mail.nih.gov.*

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Gene Regulation in Cancer Study Section.

Date: February 26–27, 2024.

Time: 9:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Manzoor A. Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetics of Health and Disease Study Section.

Date: February 26–27, 2024.

Time: 9:30 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Christopher Payne, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 2208, Bethesda, MD 20892, 301–402–3702, *christopher.payne@nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group; Integrative Vascular Physiology and Pathology Study Section.

Date: February 26–27, 2024.

Time: 9:30 a.m. to 9:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 806–7314, *shahb@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02051 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; National Centers for Translational Research in Reproduction and Infertility (P50 Clinical Trial Optional) (ZHD1 DSR–Z (55)), March 28, 2024, 9 a.m. to March 29, 2024, 5 p.m., NICHD, 6710 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on January 25, 2024, 89 FR 4966, FR Doc. 2024–01422.

Dr. Nanda has had to change the date of his ZHD1 DSR–Z (55) review meeting from 3/28 & 3/29 to 4/11 & 4/12. The meeting is closed to the public.

Dated: January 30, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02124 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; Secondary Data Analysis and Conference Grant Applications.

Date: March 6, 2024.

Time: 9:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700B Rockledge Drive, Bethesda, MD 20817.

Contact Person: Jeanette M. Hosseini, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Eye Institute, 6700 B Rockledge Drive, Bethesda, MD 20892, (301) 451–2020 *jeanetteh@mail.nih.gov*.

Name of Committee: National Eye Institute Special Emphasis Panel; Individual Training Grant Applications (Ks).

Date: March 27, 2024.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, NEI, 6700 B Rockledge Dr., Rockville, MD 20817.

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, Bethesda, MD 20817, (240) 276–5864 *jennifer.schiltz@nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: January 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02048 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; 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: National Center for Complementary and Integrative Health Special Emphasis Panel; Exploratory Clinical Trials of Mind and Body Interventions (MB).

Date: February 29–March 1, 2024.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Center for Complementary and Integrative Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Baila S. Hall, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 443–9285, *baila.hall@nih.gov*.

Marta V. Hamity, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, *marta.hamity@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: January 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02046 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; 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: National Center for Complementary and Integrative Health Special Emphasis Panel; Feasibility Trials of the NIH Music-based Interventions Toolkit for Brain Disorders of Aging (R34 Clinical Trial Required).

Date: March 6, 2024.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Center for Complementary and Integrative Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual).

Contact Person: Marta V. Hamity, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite

401, Bethesda, MD 20892, *marta.hamity@nih.gov.*

Baila S. Hall, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 443–9285, *baila.hall@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: January 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02049 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Genetic Variation and Evolution Study Section, February 15, 2024, 10:00 a.m. to February 16, 2024, 08:30 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on January 24, 2024, 89 FR 4610, Doc 2024–01290.

The GVE meeting is being amended to change the SRO from Guoqin Yu, Ph.D., to Linda Jurata, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, *linda.jurata@nih.gov* (301) 496–8032. The meeting is closed to the public.

Dated: January 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02044 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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: National Institute on Aging Special Emphasis Panel; Fetal Programming and Aging.

Date: February 27, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kaitlyn Noel Lewis Hardell, Ph.D., M.P.H., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2E405, Bethesda, MD 20892, (301) 555–1234, *kaitlyn.hardell@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 30, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–02123 Filed 2–1–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Joint Meeting of the National Advisory Councils

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

Notice is hereby given of the combined (joint) meeting on February 28, 2024, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) national advisory councils: the SAMHSA National Advisory Council (NAC), the Center for Mental Health Services NAC, the Center for Substance Abuse Prevention NAC, the Center for Substance Abuse Treatment NAC; and the two SAMHSA advisory committees: Advisory Committee for Women's Services (ACWS) and the Tribal Technical Advisory Committee (TTAC).

The meeting will include remarks from the Assistant Secretary for Mental Health and Substance Use; follow up from the JNAC meeting of August 30, 2023; updates from the individual council meetings of February 27, 2024; a presentation and discussion on the Tribal Behavioral Health Agenda process and updates; a presentation and discussion on Prevention (Naloxone); a presentation and discussion on Government Performance and Results Act (GPRA); general Council discussion and Public Comments.

The meeting is open to the public and will be held at the North Bethesda Marriott Hotel and Conference Center, 5701 Marinelli Rd., Rockville, MD 20852. Attendance by the public will be limited to space available. Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person by February 21, 2024. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact by February 21, 2024. Up to three minutes will be allotted for each presentation, as time permits.

The meeting may be accessed via telephone and remotely via Zoom platform and callers must register. To attend on site, obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: *https://snacregister.samhsa.gov,* or communicate with SAMHSA's Committee Management Officer, Carlos Castillo (see contact information below).

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at: *https://www.samhsa.gov/about-us/advisory-councils,* or by contacting Carlos Castillo. Substantive program information may be obtained after the meeting by accessing the SAMHSA Council's website at: *https://www.samhsa.gov/about-us/advisory-councils.*

Council Names:

Substance Abuse and Mental Health Services Administration National Advisory Council
Center for Mental Health Services National Advisory Council
Center for Substance Abuse Prevention National Advisory Council
Center for Substance Abuse Treatment National Advisory Council
Advisory Committee for Women's Services
Tribal Technical Advisory Committee

Date/Time/Type: February 28, 2024, 9 a.m. to 4:30 p.m. EST, Open.

Place: North Bethesda Marriott Hotel and Conference Center, 5701 Marinelli Rd., Rockville, MD 20852.

Contact: Carlos Castillo, Committee Management Officer, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276–2787, Email: *carlos.castillo@samhsa.hhs.gov*.

SAMHSA's National Advisory Councils were established to advise the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and SAMHSA's Center Directors concerning matters relating to the activities carried out by and through the Centers and the policies respecting such activities.

Under Section 501 of the Public Health Service Act, the ACWS is statutorily mandated to advise the SAMHSA Assistant Secretary for Mental Health and Substance Use and the Associate Administrator for Women's Services on appropriate activities to be undertaken by SAMHSA and its Centers with respect to women's substance abuse and mental health services.

Pursuant to Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of September 23, 2004, SAMHSA established the TTAC for working with Federally recognized Tribes to enhance the government-to-government relationship, and honor Federal trust responsibilities and obligations to Tribes and American Indian and Alaska Natives. The SAMHSA TTAC serves as an advisory body to SAMHSA.

Dated: January 24, 2024.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2024–02073 Filed 2–1–24; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Meeting of the Substance Abuse and Mental Health Services Administration National Advisory Council

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given for the meeting on February 29, 2024, of the Substance Abuse and Mental Health Services Administration National Advisory Council (SAMHSA NAC). The meeting is open to the public and can also be accessed virtually. Agenda with call-in information will be posted on the SAMHSA website prior to the meeting at: *https://www.samhsa.gov/about-us/advisory-councils/meetings.* The meeting will include, but not be limited to, remarks from the Assistant Secretary for Mental Health and Substance Use; consideration and approval of the meeting minutes of August 31, 2023; a recap of the JNAC of February 28, 2024, and Lessons Learned; a presentation and discussion on the following topics: Recovery Oriented Systems of Care (ROSC); the Release of the National Strategy for Suicide Prevention (NSSP) and how 988 fits into it; Homelessness; and general Council discussion and Public Comments.

DATES: February 29, 2024, 10 a.m. to approximately 4 p.m. EST, Open.

ADDRESSES: 5600 Fishers Lane, Rockville, Maryland 20857 (5th Floor).

FOR FURTHER INFORMATION CONTACT: Carlos Castillo, Committee Management Officer and Designated Federal Official; SAMHSA National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail); telephone: (240) 276–2787; email: *carlos.castillo@samhsa.hhs.gov*.

SUPPLEMENTARY INFORMATION: The SAMHSA NAC was established to advise the Secretary, Department of Health and Human Services (HHS), and the Assistant Secretary for Mental Health and Substance Use, SAMHSA, to improve the provision of treatments and related services to individuals with respect to substance use and to improve prevention services, promote mental health, and protect legal rights of individuals with mental illness and individuals with substance use disorders or misuse.

Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions must be forwarded to the contact person no later than 7 days before the meeting. Oral presentations from the public will be scheduled for the public comment section at the end of the council discussion. Individuals interested in making oral presentations must notify the contact person by 1 p.m. (EST), February 22, 2024. Up to three minutes will be allotted for each presentation, and as time permits, as these are presented in the order received. Public comments received will become part of the meeting records.

To obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: *https://snacregister.samhsa.gov,* or communicate with the contact person.

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at *https://www.samhsa.gov/about-us/advisory-councils/*, or by contacting Carlos Castillo.

Dated: January 24, 2024.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2024–02074 Filed 2–1–24; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Meeting of the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention National Advisory Council

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given for the meeting on February 27, 2024, of the Center for Substance Abuse Prevention National Advisory Council (CSAP NAC). The meeting is open to the public and can also be accessed virtually. Agenda with call-in information will be posted on the SAMHSA website prior to the meeting at: *https://www.samhsa.gov/about-us/advisory-councils/meetings* . The meeting will include, but not be limited to, remarks from the Assistant Secretary for Mental Health and Substance Use; approval of the meeting minutes of August 29, 2023; overview of CSAP strategic planning activities; presentations on substance use prevention priorities; Council discussion and public comments.

DATES: February 27, 2024, 9:00 a.m. to approximately 4:00 p.m. EST, Open.

ADDRESSES: 5600 Fishers Lane, Rockville, Maryland 20857 (Room 5N54).

FOR FURTHER INFORMATION CONTACT: Michelle McVay, Designated Federal Official; Substance Abuse and Mental Health Service Administration, CSAP National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail); telephone: (202) 407–2154; email: *michelle.mcvay@samhsa.hhs.gov*

SUPPLEMENTARY INFORMATION: The CSAP NAC was established to advise the Secretary, Department of Health and Human Services (HHS), and the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and the Director, CSAP, concerning matters relating to the activities carried out by

and through the Center and the policies respecting such activities.

Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions must be forwarded to the contact person no later than 7 days before the meeting. Oral presentations from the public will be scheduled for the public comment section at the end of the council discussion. Individuals interested in making oral presentations must notify the contact person by 1:00 p.m. (EST), February 20, 2024. Up to three minutes will be allotted for each presentation, and as time permits, as these are presented in the order received. Public comments received will become part of the meeting records.

To obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: *https://snacregister.samhsa.gov,* or communicate with the contact person. Meeting information and a roster of Council members may be obtained either by accessing the CSAP Council's website at *https://www.samhsa.gov/about-us/advisory-councils,* or by contacting Michelle McVay.

Dated: January 27, 2024.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2024–02063 Filed 2–1–24; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7077–N–28]

Privacy Act of 1974; System of Records

AGENCY: Office of Housing, HUD.

ACTION: Rescindment of a systems of record.

SUMMARY: The Debt Collection and Asset Management Systems (DCAMS)—Title I/Generic Debt is used to collect and maintain data needed to support activities related to the Department's collection and servicing of various HUD/FHA debts, that support collection initiatives, such as wage garnishment, offset of federal payments, pursuit of judgments, and foreclosure; and supporting defensive litigation related to foreclosure and actions to quiet title. Pursuant to OMB Circular A–108, the Department of the Housing and Urban Development's Albany Financial Operations Center is issuing this notice of its intent to delete the system of records entitled HUD/HOU–55 Debt Collection and Asset Management System (DCAMS), which consists of two sister systems Title I and Generic Debt, HUD/HOU–55.

DATES: Comments will be accepted on or before March 4, 2024. This proposed action will be effective immediately upon publication.

ADDRESSES: You may submit comments, identified by one of the following methods:

Federal e-Rulemaking Portal: https://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *https://www.regulations.gov* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White, Chief Privacy Officer, 451 Seventh Street SW, Room 10139; Washington, DC 20410; telephone number (202) 708–3054 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION: This SORN supported activities related to collecting and servicing various HUD/Federal Housing Association (FHA) debts under the Department's Title I and Generic Debt programs. The method used for retrieving records was assessed, and it was found that the system's records are retrieved using the Claim Number (also known as Case Number or Account Number) assigned to the debt. While the system has the capability to search using the debtors' Social Security Numbers, Names, and Addresses, these fields were never the primary methods of retrieval. As a result, the DCAMS system of records is being rescinded since it does not meet the legal definition. Though the systems will keep operating normally.

SYSTEM NAME AND NUMBER:

Debt Collection and Asset Management System (DCAMS), HUD/HOU–55.

HISTORY:

DCAMS Title I and Generic Debt SORN: 88 FR 7746 (February 6, 2023).

DCAMS Title I and Generic Debt SORN: 87 FR 57920 (September 22, 2022).

DCAMS Title I and Generic Debt SORN: 72 FR 63919 (November 13, 2007).

Ladonne L. White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2024–02128 Filed 2–1–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_NV_FRN_MO4500173782]

Notice To Segregate Lands From Mineral Entry for the Proposed Libra Solar Project in Mineral County, Nevada

AGENCY: Bureau of Land Management, Department of Interior.

ACTION: Notice of segregation.

SUMMARY: Through this notice, the Bureau of Land Management (BLM) is segregating public lands for the Libra Solar Project right-of-way application from appropriation under the public land laws, including the Mining Law, for a period of 2 years from the date of publication of this notice in the **Federal Register**, subject to valid existing rights. This segregation is to allow for the orderly administration of the public lands to facilitate consideration of development of renewable energy resources. The public lands segregated by this notice total 120 acres.

DATES: This segregation for the lands identified in this notice is effective on February 2, 2024.

FOR FURTHER INFORMATION CONTACT: Terah Malsam, Realty Specialist, telephone (775) 885–6153; address 5665 Morgan Mill Road, Carson City, NV 89701; email *blm_nv_ccdo_libra_solar@blm.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 for contacting Melanie Hornsby. 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: On April 24, 2023, the Notice of Intent to segregate lands and prepare an environmental impact statement for the proposed Libra Solar Project was published in the **Federal Register** (88 FR 24827). This announced the segregation of 5,500 acres of public lands for the proposed project. This notice effectively adds 120 acres to the segregation for a total of 5,620 acres of public land.

Regulations found at 43 CFR 2091.3–1(e) and 43 CFR 2804.25(f) allow the BLM to temporarily segregate public lands within a right-of-way application area for solar energy development from the operation of the public land laws, including the Mining Law, by publication of a **Federal Register** notice. The BLM uses this temporary segregation authority to preserve its ability to approve, approve with modifications, or deny proposed rights-of-way, and to facilitate the orderly administration of the public lands. This temporary segregation is subject to valid existing rights, including existing mining claims, located before this segregation notice. Licenses, permits, cooperative agreements, or discretionary land use authorizations of a temporary nature that would not impact lands identified in this notice may be allowed with the approval of an authorized officer of the BLM during the segregation period. The lands segregated under this notice are legally described as follows:

Mount Diablo Meridian, Nevada

T. 12 N., R. 27 E.,
Sec. 32, N½SE¼;
Sec. 35, NE¼ SW¼.

The areas described aggregate 120 acres, according to the official plat of the survey on file with the BLM.

As provided in the regulations, the segregation of lands in this notice will not exceed 2 years from the date of publication unless extended for up to 2 additional years through publication of a new notice in the **Federal Register**. Termination of the segregation occurs on the earliest of the following dates: upon issuance of a decision by the authorized officer granting, granting with modifications, or denying the application for a ROW; automatically at the end of the segregation; or upon publication of a **Federal Register** notice of termination of the segregation.

Upon termination of segregation of these lands, all lands subject to this segregation would automatically reopen to appropriation under the public land laws.

(Authority: 43 CFR 2091.3–1e and 43 CFR 2804.25(f))

Kimberly D. Dow,

District Manager.

[FR Doc. 2024–02066 Filed 2–1–24; 8:45 am]

BILLING CODE 4331–21–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2024–0006]

Notice of Availability of a Draft Environmental Assessment for Additional Site Assessment Activities on Beacon Wind, LLC's Renewable Energy Lease OCS–A 0520

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) announces the availability of the draft environmental assessment (EA) to analyze the reasonably foreseeable impacts from additional site assessment plan (SAP) activities in Lease Area OCS–A 0520 offshore Massachusetts. Beacon Wind, LLC (Beacon Wind), the leaseholder, requests to conduct additional site assessment activities in the lease area that were not analyzed in the initial EA titled ''Commercial Wind Lease Issuance and Site Assessment Activities on the Atlantic Outer Continental Shelf Offshore Massachusetts'' (2014 EA). The draft EA analyzes the potential environmental impacts of the proposed site assessment activities, which consist of 35 deployments and removals of a single suction bucket foundation at 26 locations within the Lease Area to gather information to support the engineering design of wind turbine and offshore substation foundations that would potentially be installed within the Lease Area for a future Beacon Wind project. This notice of availability (NOA) announces the start of the public review and comment period, as well as the dates and times for public meetings on the draft EA. After BOEM holds the public meetings and addresses public comments submitted during the review period, BOEM will publish a final EA. The EA will inform BOEM's decision whether to approve the site assessment plan amendment for additional site assessment activities.

DATES: Comments must be received no later than March 4, 2024. BOEM's virtual public meetings will be held on the following dates at the times (eastern time) indicated.

- Friday, February 23, 2024; 1:00 p.m.
- Wednesday, February 28, 2024; 5:00 p.m.

Registration for the virtual public meeting is required and may be completed at *https://www.boem.gov/renewable-energy/state-activities/beacon-wind.* Meeting information will be sent to registrants via their email address provided during registration.

ADDRESSES: The draft EA and detailed information about the proposed site assessment activities can be found on BOEM's website at: *https://www.boem.gov/renewable-energy/state-activities/beacon-wind.* Comments can be submitted in any of the following ways:

- Orally or in written form during any of the public meetings identified in this NOA.
- In written form by mail or any other delivery service, enclosed in an envelope labeled ''Beacon Wind SAP EA'' and addressed to Chief, Office of Renewable Energy Programs, Bureau of Ocean Energy Management, 45600 Woodland Road, Mailstop VAM–OREP, Sterling, VA 20166.
- *Through the regulations.gov web portal:* Navigate to *https://www.regulations.gov* and search for Docket No. BOEM–2024–0006. Click on the ''Comment'' button below the document link. Enter your information and comment, then click ''Submit Comment.''

For more information about submitting comments, please see ''*Information on Submitting Comments*'' under the **SUPPLEMENTARY INFORMATION** heading below.

FOR FURTHER INFORMATION CONTACT: Laura Lee Wolfson, BOEM Office of Renewable Energy Programs, 45600 Woodland Road, Sterling, Virginia 20166, (703) 787–1433 or *lauralee.wolfson@boem.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Action: The draft EA analyzes two alternatives: the proposed action, which is approving the additional site assessment activities proposed in the Beacon Wind SAP Amendment to the Lease Area, and the no action alternative. The EA considers the reasonably foreseeable environmental consequences associated with the deployment and recovery of suction bucket foundations to further assess the site conditions and gather information to support the engineering design of wind turbine and offshore substation foundations that would potentially be installed within the Lease Area for the proposed Beacon Wind project. BOEM prepared an EA for this proposed action in order to assist the

agency's planning and decision-making (40 CFR 1501.5(b)).

Availability of the draft EA: The draft EA and associated information are available on BOEM's website at: *https://www.boem.gov/renewable-energy/state-activities/beacon-wind.* If you require a digital copy on a flash drive or paper copy, BOEM may provide one upon request, if supplies are available. You may request a flash drive or paper copy of the draft EA by contacting Laura Lee Wolfson at (703) 787–1662 or *lauralee.wolfson@boem.gov.*

Cooperating Agencies: The following Federal agency will participate as cooperating agency in the preparation of the EA: the Bureau of Safety and Environmental Enforcement.

Information on Submitting Comments

a. Freedom of Information Act

BOEM will protect privileged or confidential information that you submit when required by the Freedom of Information Act (FOIA). Exemption 4 of FOIA applies to trade secrets and commercial or financial information that is privileged or confidential. If you wish to protect the confidentiality of such information, clearly label it and request that BOEM treat it as confidential. BOEM will not disclose such information if BOEM determines under 30 CFR 585.114(b) that it qualifies for exemption from disclosure under FOIA. Please label privileged or confidential information ''Contains Confidential Information'' and consider submitting such information as a separate attachment.

BOEM will not treat as confidential any aggregate summaries of such information or comments not containing such privileged or confidential information. Information that is not labeled as privileged or confidential may be regarded by BOEM as suitable for public release.

b. Personally Identifiable Information

BOEM discourages anonymous comments. Please include your name and address as part of your comment. You should be aware that your entire comment, including your name, address, and any other personally identifiable information (PII) that you include, may be made publicly available. All comments from identified individuals, businesses, and organizations will be available for public viewing on *regulations.gov.* Note that BOEM will make available for public inspection all comments, in their entirety, submitted by organizations and businesses, or by individuals identifying themselves as representatives of organizations or businesses.

For BOEM to consider withholding your PII from disclosure, you must identify any information contained in your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequences of the disclosure of information, such as embarrassment, injury, or other harm. Even if BOEM withholds your information in the context of this notice, your comment is subject to FOIA. If your comment is requested under FOIA, BOEM will withhold your information only if it determines that one of FOIA's exemptions to disclosure applies. Such a determination will be made in accordance with the Department's FOIA regulations and applicable law.

c. Section 304 of the NHPA (54 U.S.C. 307103(a))

After consultation with the Secretary, BOEM is required to withhold the location, character, or ownership of historic resources if it determines that disclosure may, among other things, risk harm to the historic resources or impede the use of a traditional religious site by practitioners. Tribal entities should designate information that falls under section 304 of NHPA as confidential.

Authority: 42 U.S.C. 4231 *et seq.* (NEPA, as amended) and 40 CFR 1506.6.

Karen Baker,

Chief, Office of Renewable Energy Programs, Bureau of Ocean Energy Management.

[FR Doc. 2024–02065 Filed 2–1–24; 8:45 am]

BILLING CODE 4340–98–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 245S180110; S2D2S SS08011000 SX064A000 24XS501520; OMB Control Number 1029–0063]

Agency Information Collection Activities; Fee Collection and Coal Production Reporting and Form OSM–1, Coal Reclamation Fee Report

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before March 4, 2024.

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. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0063 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at (202) 208–2716. 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. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on September 12, 2023 (88 FR 62599). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The information is used to maintain a record of coal produced for sale, transfer, or use nationwide each calendar quarter, the method of coal removal and the type of coal, and the basis for coal tonnage reporting in compliance with 30 CFR 870 and section 401 of Pub. L. 95–87. Individual reclamation fee payment liability is based on this information. Without the collection of this information, OSMRE could not implement its regulatory responsibilities and collect the fee.

Title of Collection: Fee Collection and Coal Production Reporting and form OSM–1, Coal Reclamation Fee Report.

OMB Control Number: 1029–0063.

Form Number: OSM–1.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses.

Total Estimated Number of Annual Respondents: 340.

Total Estimated Number of Annual Responses: 5,082.

Estimated Completion Time per Response: 4 minutes to 15 minutes, depending on activity.

Total Estimated Number of Annual Burden Hours: 413.

Respondent's Obligation: Mandatory.

Frequency of Collection: Annual.

Total Estimated Annual Nonhour Burden Cost: $158,160.

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.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Office of Surfacing Mining Reclamation and Enforcement.

[FR Doc. 2024–02056 Filed 2–1–24; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF JUSTICE

[OMB Number 1123–0014]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Application for Certificate of Pardon for Simple Possession of Marijuana

AGENCY: Office of the Pardon Attorney, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office of the Pardon Attorney, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 2, 2024.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kira Gillespie, Deputy Pardon Attorney, Office of the Pardon Attorney, 950 Pennsylvania Avenue NW, Main Justice—RFK Building, Washington, DC 20530; *uspardon.attorney@usdoj.gov;* 202–616–6070.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: The President issued a Proclamation on Granting Pardon for the Offense of Simple Possession Marijuana (Proclamation) on October 6, 2022. In that proclamation, he directed the Attorney General, acting through the Pardon Attorney, to develop procedures to ''administer and effectuate the issuance of certificates of pardon to eligible applicants . . . . as soon as reasonably practicable.'' The Proclamation specifically commands the Pardon Attorney to ''develop and announce application procedures.'' Accordingly, the Pardon Attorney had developed the subject form to collect information from potential pardon recipients, which was granted full approval under OMB Number 0123–0014, on September 5, 2023.

On December 22, 2023, the President issued a second proclamation that broadened the pardon to additional persons convicted of simple possession of marijuana under Federal or D.C. code law.

The second proclamation expanded the statutes of conviction eligible for a pardon, the circumstances under which eligible persons have been pardoned, and the time frame covered by the pardon. Consequently, the number of persons eligible to apply for a certificate proving the pardon has also increased.

Importantly, there is virtually no change to the burden that an individual applicant will incur: the application continues to ask applicants to confirm that the petitioner is U.S. citizen or lawful permanent resident who was lawfully in the country at the time the marijuana offense occurred; information regarding their current citizenship status, and if naturalized, the date or if a lawful permanent resident, the date that status was attained; the alien registration or citizenship number of a

lawful permanent resident or naturalized citizen applicant; information regarding the specific court in which the applicant was charged or convicted and the date of said conviction, if any; information regarding the applicant's race, gender, and ethnicity; identifying information regarding the applicant's date and place of birth; and documentation of the applicant's charge or convictions.

The information collected from the Certificate Application will primarily be used to determine whether the applicant qualifies for pardon under the terms of the Proclamation. The information may also be used to provide statistical analysis of the demographics of pardon recipients and applicants.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *The Title of the Form/Collection:* Application for Certificate of Pardon for Simple Possession of Marijuana.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no agency form number for this collection. The applicable component within the Department of Justice is the Office of the Pardon Attorney.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: Individuals or households. The obligation to respond is voluntary.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Available information suggests that the new proclamation has approximately doubled the potential applicant pool. However, the review of the applications received within a 10-month time frame indicates that 1,500 applicants annually is a reasonable projection. We estimate an average of 120 minutes for each applicant to respond to the collection.

6. *An estimate of the total annual burden (in hours) associated with the collection:* Considering the above projected figures, we estimate hours of annual burden to the public.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* $0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
Application	1,500	1/annually	1,500	2 hrs	3,000
Unduplicated Totals	*1,500*		*1,500*		*3,000*

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: January 30, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–02133 Filed 2–1–24; 8:45 am]

BILLING CODE 4410–29–P

DEPARTMENT OF JUSTICE

[OMB Number 1123–0NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection; Application for Remission of Financial Penalties

AGENCY: Office of the Pardon Attorney, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office of the Pardon Attorney, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 2, 2024.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kira Gillespie, Deputy Pardon Attorney, Office of the Pardon Attorney, 950 Pennsylvania Avenue NW, Main Justice—RFK Building, Washington, DC 20530; *uspardon.attorney@usdoj.gov;* 202–616–6070.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: Applicants seeking remission of financial penalties by the President will be asked to respond to this collection. The principal purpose for collecting this information is to enable the Office of the Pardon Attorney to process applicants' requests for remission of financial penalties. The information is necessary to verify applicants' identities, conduct investigation of the applicants' backgrounds, criminal records, and conduct since their conviction, and to provide notice to the Federal Bureau of Investigation, U.S. Attorneys' Offices, U.S. Probation Offices, and Federal courts in the event of grants of executive clemency.

Overview of This Information Collection

1. *Type of Information Collection:* New collection.

2. *The Title of the Form/Collection:* Application for Remission of Financial Penalties.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no agency form number for this collection. The applicable component within the Department of Justice is the Office of the Pardon Attorney.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: Individuals or households. The obligation to respond is voluntary.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Available information suggests that potentially 500 to 1,000 applicants will complete petitions annually. We estimate an average of 180 minutes for each applicant to respond to the collection.

6. *An estimate of the total annual burden (in hours) associated with the collection:* Considering the above projected figures, we estimate 1,500 to 3,000 hours of annual burden to the public.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* $0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
Application	1,000	1/annually	1,000	180 min	3,000
Unduplicated Totals	*1,000*		*1,000*		*3,000*

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: January 30, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–02134 Filed 2–1–24; 8:45 am]

BILLING CODE 4410–29–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standard

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before March 4, 2024.

ADDRESSES: You may submit comments identified by Docket No. MSHA–2023–0054 by any of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for MSHA–2023–0054.

2. *Fax:* 202–693–9441.

3. *Email: petitioncomments@dol.gov.*

4. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, 4th Floor West, Arlington, Virginia 22202–5452.

Attention: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk, 4th Floor West. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing, and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2023–025–C.

Petitioner: Panther Creek Mining, LLC, 903 Dawes Hollow, Dawes, West Virginia 25054.

Mine: Winchester 2 Mine, MSHA ID No. 46–09615, located in Kanawha County, West Virginia.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

Modification Request: The petitioner requests a modification of 30 CFR 75.500(d) to permit the use of non-permissible battery-powered electronic surveying equipment in or inby the last open crosscut.

The petitioner states that:

(a) The mine utilizes the continuous miner method of mining.

(b) In order to comply with requirements of 30 CFR 75.372 and 30 CFR 75.1200, use of the most practical and accurate surveying equipment is necessary.

(c) Mechanical surveying equipment has been obsolete for several years. Such equipment of acceptable quality is not commercially available. It is difficult to have such equipment serviced or repaired.

(d) Battery-powered electronic surveying equipment is, at a minimum,

8–10 times more accurate than mechanical equipment.

(e) Accurate surveying is critical to the safety of the miners at the Winchester 2 Mine.

(f) Underground mining by its nature, size and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner. Use of electronic surveying equipment provides significant safety benefits.

The petitioner proposes the following alternative method:

(a) Non-permissible electronic surveying equipment to be used includes:

(1) Topcom GM 52 Total Station.

(b) The equipment used is low voltage or battery-powered non-permissible total stations and theodolites. All non-permissible electronic total stations and theodolites shall have an IP 66 or greater rating.

(c) The operator shall maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept, or in the location where the surveying record books are kept. The logbook shall contain the date of manufacture and/or purchase of each piece of electronic surveying equipment. The logbook shall be made available to MSHA upon request.

(d) All non-permissible electronic surveying equipment to be used in or inby the last open crosscut shall be examined by the person to operate the equipment prior to taking the equipment underground to ensure the equipment is being maintained in safe operating condition. These examinations shall include:

(1) Checking the instrument for any physical damage and the integrity of the case;

(2) Removing the battery and inspecting for corrosion;

(3) Inspecting the contact points to ensure a secure connection to the battery;

(4) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(5) Checking the battery compartment cover or battery attachment to ensure that is securely fastened.

The results of this examination shall be recorded in the logbook.

(e) The equipment shall be examined at least weekly by a qualified person as defined in 30 CFR 75.153. The examination results shall be recorded weekly in the equipment's logbook. These records shall be retained for 1 year.

(f) The operator shall ensure that all non-permissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Date of service shall be recorded in the equipment's logbook and shall include a description of the work performed.

(g) The non-permissible electronic surveying equipment to be used in or inby the last open crosscut shall not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of the Proposed Decision and Order (PDO) granted by MSHA.

(h) Non-permissible electronic surveying equipment shall not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more of methane is detected while the non-permissible electronic surveying equipment is being used, the equipment shall be de-energized immediately and withdrawn outby the last open crosscut. All requirements of 30 CFR 75.323 shall be complied with prior to entering in or inby the last open crosscut.

(i) Before setting up and energizing nonpermissible electronic surveying equipment in or inby the last open crosscut, the surveyor(s) shall conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the nonpermissible electronic surveying equipment shall not be energized until sufficient rock dust has been applied and/or the accumulations of float coal dust have been removed. If nonpermissible electronic surveying equipment is to be used in an area that has not been rock-dusted within 40 feet of a working face where a continuous mining machine is used to extract coal, the area shall be rock-dusted prior to energizing the nonpermissible electronic surveying equipment.

(j) All hand-held methane detectors shall be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors shall provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing any of the non-permissible electronic surveying equipment in or inby the last open crosscut, methane tests shall be made in accordance with 30 CFR 75.323(a).

(l) All areas to be surveyed must be pre-shifted according to 30 CFR 75.360 prior to surveying. If the area was not pre-shifted, a supplemental examination according to 30 CFR 75.361 shall be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 30 CFR 75.361, additional examination is not required.

(m) A qualified person as defined in 30 CFR 75.151 shall continuously monitor for methane immediately before and during the use of non-permissible electronic surveying equipment in or inby the last open crosscut. A second person in the surveying crew, if there are two people in the crew, shall also continuously monitor for methane. That person shall be a qualified person as defined in 30 CFR 75.151 or be in the process of being trained to be a qualified person but have yet to ''make such tests for a period of 6 months'' as required by 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew shall become qualified to continue on the surveying crew. If the surveying crew consists of only one person, the person shall monitor for methane with two separate devices.

(n) Batteries contained in the non-permissible electronic surveying equipment shall be changed out or charged in intake air outby the last open crosscut. Replacement batteries for the non-permissible electronic surveying equipment shall be carried only in the electronic equipment carrying case spare battery compartment. Before each surveying shift, all batteries for the non-permissible electronic surveying equipment shall be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using non-permissible electronic surveying equipment in or inby the last open crosscut, the surveyor shall confirm by measurement or by inquiry of the person in charge of the section that the air quantity on the section, on that shift, in the last open crosscut is at least the minimum quantity required by the mine's ventilation plan.

(p) Personnel engaged in the use of non-permissible electronic surveying equipment shall be properly trained to recognize the hazards and limitations associated with the use of non-permissible electronic surveying equipment in areas where methane could be present.

(q) All members of the surveying crew shall receive specific training on the terms and conditions of the PDO granted by MSHA before using non-permissible electronic surveying equipment in or inby the last open crosscut. A record of the training shall be kept with the other training records.

(r) Within 60 days after the PDO granted by MSHA becomes final, the

operator shall submit proposed revisions for its approved 30 CFR part 48 training plans to the Coal Mine Safety and Health District Manager. These proposed revisions shall specify initial and refresher training regarding the terms and conditions of the PDO. When training is conducted on the terms and conditions of the PDO, a MSHA Certificate of Training (Form 5000–23) shall be completed and shall include comments indicating it was surveyor training.

(s) The operator shall replace or retire from service any non-permissible electronic surveying instrument acquired prior to December 31, 2004, within 1 year of the PDO granted by MSHA becomes final. Within 3 years of the date the PDO becomes final, the operator shall replace or retire from service any theodolite acquired more than 5 years prior to the date the PDO became final and any total station or other electronic surveying equipment identified in the PDO acquired more than10 years prior to the date the PDO became final. After 5 years, the operator shall maintain a cycle of purchasing new electronic surveying equipment so that theodolites shall be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment shall be no older than 10 years from date of manufacture.

(t) The operator is responsible for ensuring that all surveying contractors hired by the operator use non-permissible electronic surveying equipment in accordance with the requirements of paragraph (s) of the PDO granted by MSHA. The conditions of use specified in the PDO shall apply to all non-permissible electronic surveying equipment used in or inby the last open crosscut, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) Non-permissible surveying electronic surveying equipment may be used when production is occurring, subject to these conditions:

(1) On a mechanized mining unit (MMU) where production is occurring, non-permissible electronic surveying equipment shall not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

(2) Production may continue while non-permissible electronic surveying equipment is used if the surveying equipment is used in a separate split of air from where production is occurring.

(3) Non-permissible electronic surveying equipment shall not be used in a split of air ventilating an MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

(4) If a surveyor must disrupt ventilation while surveying, the surveyor shall cease surveying and communicate to the section foreman that ventilation must be disrupted. Production shall stop while ventilation is disrupted. Ventilation controls shall be reestablished immediately after the disruption is no longer necessary. Production shall only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans and other applicable laws, standards, or regulations.

(5) Any disruption in ventilation shall be recorded in the logbook required by the PDO granted by MSHA. The logbook shall include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption, the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

(6) All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations shall receive training in accordance with 30 CFR 48.7 on the requirements of the PDO granted by MSHA within 60 days of the date the PDO becomes final. Such training shall be completed before any non-permissible electronic surveying equipment can be used while production is occurring. The operator shall keep a record of such training and provide it to MSHA upon request.

(7) The operator shall provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator shall train new miners on the requirements of the PDO granted by MSHA in accordance with 30 CFR 48.5 and shall train experienced miners, as defined in 30 CFR 48.6, on the requirements of the PDO in accordance with 30 CFR 48.6. The operator shall keep a record of such training and provide it to MSHA upon request.

The petitioner asserts that the alternate method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2024–02071 Filed 2–1–24; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petition for Modification of Application of Existing Mandatory Safety Standard

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA's Office of Standards, Regulations, and Variances on or before March 4, 2024.

ADDRESSES: You may submit comments identified by Docket No. MSHA–2023–0055 by any of the following methods:

1. *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments for MSHA–2023–0055.
2. *Fax:* 202–693–9441.
3. *Email: petitioncomments@dol.gov.*
4. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, 4th Floor West, Arlington, Virginia 22202–5452.

Attention: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk, 4th Floor West. Individuals may inspect copies of the petition and comments during normal business hours at the address listed above. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor's COVID–19 policy. Special health precautions may be required.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Petitionsformodification@dol.gov* (email), or 202–693–9441 (fax). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and title 30 of the Code of Federal Regulations (CFR) part 44 govern the application, processing,

and disposition of petitions for modification.

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. The application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, sections 44.10 and 44.11 of 30 CFR establish the requirements for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2023–026–C.

Petitioner: Panther Creek Mining, LLC, 903 Dawes Hollow, Dawes, West Virginia 25054.

Mine: Winchester 2 Mine, MSHA ID No. 46–09615, located in Kanawha County, West Virginia.

Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

Modification Request: The petitioner requests a modification of 30 CFR 75.507–1(a) to permit the use of non-permissible battery-powered electronic surveying equipment in return air outby the last open crosscut.

The petitioner states that:

(a) The mine utilizes the continuous miner method of mining.

(b) In order to comply with requirements of 30 CFR 75.372 and 30 CFR 75.1200, use of the most practical and accurate surveying equipment is necessary.

(c) Mechanical surveying equipment has been obsolete for several years. Such equipment of acceptable quality is not commercially available. It is difficult to have such equipment serviced or repaired.

(d) Battery-powered electronic surveying equipment is, at a minimum, 8–10 times more accurate than mechanical equipment.

(e) Accurate surveying is critical to the safety of the miners at the Winchester 2 Mine.

(f) Underground mining by its nature, size and complexity of mine plans requires that accurate and precise measurements be completed in a prompt and efficient manner. Use of electronic surveying equipment provides significant safety benefits.

The petitioner proposes the following alternative method:

(a) Non-permissible battery-powered electronic surveying equipment to be used includes:

(1) Topcom GM 52 Total Station.

(b) The equipment used is low voltage or battery-powered non-permissible total stations and theodolites. All non-permissible electronic total stations and theodolites shall have an IP 66 or greater rating.

(c) The operator shall maintain a logbook for electronic surveying equipment with the equipment, or in the location where mine record books are kept or in the location where the surveying record books are kept. The logbook shall contain the date of manufacture and/or purchase of each piece of electronic surveying equipment. The logbook shall be made available to MSHA upon request.

(d) All non-permissible electronic surveying equipment to be used in return air outby the last open crosscut shall be examined by the person to operate the equipment prior to taking the equipment underground to ensure the equipment is being maintained in safe operating condition. These examinations shall include:

(1) Checking the instrument for any physical damage and the integrity of the case;

(2) Removing the battery and inspecting for corrosion;

(3) Inspecting the contact points to ensure a secure connection to the battery;

(4) Reinserting the battery and powering up and shutting down to ensure proper connections; and

(5) Checking the battery compartment cover or batter attachment to ensure that is securely fastened.

The results of this examination shall be recorded in the logbook.

(e) The equipment shall be examined at least weekly by a qualified person as defined in 30 CFR 75.153. The examination results shall be recorded weekly in the equipment's logbook. These records shall be retained for 1 year.

(f) The operator shall ensure that all non-permissible electronic surveying equipment is serviced according to the manufacturer's recommendations. Date of service shall be recorded in the equipment's logbook and shall include a description of the work performed.

(g) The non-permissible electronic surveying equipment to be used in return air outby the last open crosscut shall not be put into service until MSHA has initially inspected the equipment and determined that it is in compliance with all the terms and conditions of the Proposed Decision and Order (PDO) granted by MSHA.

(h) Non-permissible electronic surveying equipment shall not be used if methane is detected in concentrations at or above 1.0 percent. When 1.0 percent or more of methane is detected while the non-permissible electronic surveying equipment is being used, the equipment shall be de-energized immediately and withdrawn out of the return air outby the last open crosscut. All requirements of 30 CFR 75.323 shall be complied with prior to entering in return air outby the last open crosscut.

(i) Before setting up and energizing nonpermissible electronic surveying equipment in return air outby the last open crosscut, the surveyor(s) shall conduct a visual examination of the immediate area for evidence that the area appears to be sufficiently rock-dusted and for the presence of accumulated float coal dust. If the rock-dusting appears insufficient or the presence of accumulated float coal dust is observed, the nonpermissible electronic surveying equipment shall not be energized until sufficient rock dust has been applied and/or the accumulations of float coal dust have been removed. If nonpermissible electronic surveying equipment is to be used in an area that has not been rock-dusted within 40 feet of a working face where a continuous mining machine is used to extract coal, the area shall be rock-dusted prior to energizing the non-permissible electronic surveying equipment.

(j) All hand-held methane detectors shall be MSHA-approved and maintained in permissible and proper operating condition as defined by 30 CFR 75.320. All methane detectors shall provide visual and audible warnings when methane is detected at or above 1.0 percent.

(k) Prior to energizing any of the non-permissible electronic surveying equipment in return air outby the last open crosscut, methane tests shall be made in accordance with 30 CFR 75.323(a).

(l) All areas to be surveyed must be pre-shifted according to 30 CFR 75.360 prior to surveying. If the area was not pre-shifted, a supplemental examination according to 30 CFR 75.361 shall be performed before any non-certified person enters the area. If the area has been examined according to 30 CFR 75.360 or 30 CFR 75.361, additional examination is not required.

(m) A qualified person as defined in 30 CFR 75.151 shall continuously

monitor for methane immediately before and during the use of non-permissible electronic surveying equipment in return air outby the last open crosscut. A second person in the surveying crew, if there are two people in the crew, shall also continuously monitor for methane. That person shall be a qualified person as defined in 30 CFR 75.151 or be in the process of being trained to be a qualified person but have yet to ''make such tests for a period of 6 months'' as required by 30 CFR 75.150. Upon completion of the 6-month training period, the second person on the surveying crew shall become qualified to continue on the surveying crew. If the surveying crew consists of only one person, the person shall monitor for methane with two separate devices.

(n) Batteries contained in the non-permissible electronic surveying equipment shall be changed out or charged in intake air outby the last open crosscut. Replacement batteries for the non-permissible electronic surveying equipment shall be carried only in the electronic equipment carrying case spare battery compartment. Before each surveying shift, all batteries for the non-permissible electronic surveying equipment shall be charged sufficiently so that they are not expected to be replaced on that shift.

(o) When using non-permissible electronic surveying equipment in return air outby the last open crosscut, the surveyor shall confirm by measurement or by inquiry of the person in charge of the section that the air quantity on the section, on that shift, in in return air outby the last open crosscut is at least the minimum quantity required by the mine's ventilation plan.

(p) Personnel engaged in the use of non-permissible electronic surveying equipment shall be properly trained to recognize the hazards and limitations associated with the use of non-permissible electronic surveying equipment in areas where methane could be present.

(q) All members of the surveying crew shall receive specific training on the terms and conditions of the PDO granted by MSHA before using non-permissible electronic surveying equipment in return air outby the last open crosscut. A record of the training shall be kept with the other training records.

(r) Within 60 days after the PDO granted by MSHA becomes final, the operator shall submit proposed revisions for its approved 30 CFR part 48 training plans to the Coal Mine Safety and Health District Manager. These proposed revisions shall specify initial and refresher training regarding the terms and conditions of the PDO. When training is conducted on the terms and conditions of the PDO, a MSHA Certificate of Training (Form 5000–23) shall be completed and shall include comments indicating it was surveyor training.

(s) The operator shall replace or retire from service any non-permissible electronic surveying instrument acquired prior to December 31, 2004, within 1 year of the PDO granted by MSHA becomes final. Within 3 years of the date the PDO becomes final, the operator shall replace or retire from service any theodolite acquired more than 5 years prior to the date the PDO became final and any total station or other electronic surveying equipment identified in the PDO acquired more than10 years prior to the date the PDO became final. After 5 years, the operator shall maintain a cycle of purchasing new electronic surveying equipment so that theodolites shall be no older than 5 years from the date of manufacture and total stations and other electronic surveying equipment shall be no older than 10 years from date of manufacture.

(t) The operator is responsible for ensuring that all surveying contractors hired by the operator use non-permissible electronic surveying equipment in accordance with the requirements of paragraph (s) of the PDO granted by MSHA. The conditions of use specified in the PDO shall apply to all non-permissible electronic surveying equipment used in return air outby the last open crosscut, regardless of whether the equipment is used by the operator or by an independent contractor.

(u) Non-permissible electronic surveying equipment may be used when production is occurring, subject to these conditions:

(1) On a mechanized mining unit (MMU) where production is occurring, non-permissible electronic surveying equipment shall not be used downwind of the discharge point of any face ventilation controls, such as tubing (including controls such as ''baloney skins'') or curtains.

(2) Production may continue while non-permissible electronic surveying equipment is used if the surveying equipment is used in a separate split of air from where production is occurring.

(3) Non-permissible electronic surveying equipment shall not be used in a split of air ventilating a MMU if any ventilation controls will be disrupted during such surveying. Disruption of ventilation controls means any change to the mine's ventilation system that causes the ventilation system not to function in accordance with the mine's approved ventilation plan.

(4) If a surveyor must disrupt ventilation while surveying, the surveyor shall cease surveying and communicate to the section foreman that ventilation must be disrupted. Production shall stop while ventilation is disrupted. Ventilation controls shall be reestablished immediately after the disruption is no longer necessary. Production shall only resume after all ventilation controls are reestablished and are in compliance with approved ventilation or other plans and other applicable laws, standards, or regulations.

(5) Any disruption in ventilation shall be recorded in the logbook required by the PDO granted by MSHA. The logbook shall include a description of the nature of the disruption, the location of the disruption, the date and time of the disruption, the date and time the surveyor communicated the disruption to the section foreman, the date and time production ceased, the date and time ventilation was reestablished, and the date and time production resumed.

(6) All surveyors, section foremen, section crew members, and other personnel who will be involved with or affected by surveying operations shall receive training in accordance with 30 CFR 48.7 on the requirements of the PDO granted by MSHA within 60 days of the date the PDO becomes final. Such training shall be completed before any non-permissible electronic surveying equipment can be used while production is occurring. The operator shall keep a record of such training and provide it to MSHA upon request.

(7) The operator shall provide annual retraining to all personnel who will be involved with or affected by surveying operations in accordance with 30 CFR 48.8. The operator shall train new miners on the requirements of the PDO granted by MSHA in accordance with 30 CFR 48.5 and shall train experienced miners, as defined in 30 CFR 48.6, on the requirements of the PDO in accordance with 30 CFR 48.6. The operator shall keep a record of such training and provide it to MSHA upon request.

The petitioner asserts that the alternate method proposed will at all times guarantee no less than the same measure of protection afforded the miners under the mandatory standard.

Song-ae Aromie Noe,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2024–02090 Filed 2–1–24; 8:45 am]

BILLING CODE 4520–43–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's Committee on Strategy hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Wednesday, February 7, 2024, from 4:00–5:00 p.m. Eastern.

PLACE: This meeting will be via videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Chair's Opening Remarks; Presentation and discussion of NSF's FY 2025 Annual Performance Plan and FY 2023 Annual Performance Report.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Christopher Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2024–02211 Filed 1–31–24; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2024–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of February 5, 12, 19, 26, and March 4, 11, 2024. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555, at 301–415–1969, or by email at *Betty.Thweatt@nrc.gov* or *Samantha.Miklaszewski@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of February 5, 2024

There are no meetings scheduled for the week of February 5, 2024.

Week of February 12, 2024—Tentative

There are no meetings scheduled for the week of February 12, 2024.

Week of February 19, 2024—Tentative

Thursday, February 22, 2024

9:00 a.m. Update on Research and Test Reactors Regulatory Program (Public Meeting) (Contact: Wesley Deschaine: 404–997–5301)

Additional Information: The meeting will be held in the Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—*https://video.nrc.gov/.*

Week of February 26, 2024—Tentative

There are no meetings scheduled for the week of February 26, 2024.

Week of March 4, 2024—Tentative

There are no meetings scheduled for the week of March 4, 2024.

Week of March 11, 2024—Tentative

There are no meetings scheduled for the week of March 11, 2024.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: January 31, 2024.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2024–02203 Filed 1–31–24; 11:15 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Survey of Nonparticipating Single Premium Group Annuity Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information (OMB control number 1212–0030, expiring July 31, 2024). The purpose of this information collection is to survey insurance company rates for pricing annuity contracts to obtain information needed to set actuarial assumptions. The American Council of Life Insurers conducts this voluntary survey for PBGC. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments should be submitted by April 2, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the website instructions for submitting comments.
- *Email: paperwork.comments@pbgc.gov.* Refer to Survey of Insurance Company Rates or OMB control number 1212–0030 in the subject line.
- *Mail or Hand Delivery:* Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101.

Commenters are strongly encouraged to submit comments electronically. Commenters who submit comments on paper by mail should allow sufficient time for mailed comments to be received before the close of the comment period.

All submissions received must include the agency's name (Pension Benefit Guaranty Corporation, or PBGC) and refer to Survey of Insurance Company Rates or OMB control number 1212–0030. All comments received will be posted without change to PBGC's website, *www.pbgc.gov,* including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information.

Copies of the collection of information may be obtained without charge by writing to the Disclosure Division, (*disclosure@pbgc.gov*), Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101; or, calling 202–229–4040 during normal business hours. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT: Gregory Katz (*katz.gregory@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101, 202–229–3829. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: PBGC's regulations prescribe actuarial valuation methods and assumptions (including interest rate assumptions) to be used to determine the actuarial present value of benefits under single-employer plans in involuntary or distress terminations (29 CFR part 4044) and the present value of benefits and certain assets under multiemployer plans that undergo a mass withdrawal of contributing employers (29 CFR part 4281). In each month immediately preceding the start of a new calendar quarter, PBGC publishes the interest assumption to be used under those regulations for plans terminating or undergoing mass withdrawal during the next quarter.

The interest assumption is intended to reflect current conditions in the group annuity markets. To determine the interest assumption, PBGC gathers premium rate data from insurance companies that are providing annuity contracts to terminating pension plans through a quarterly survey. The American Council of Life Insurers (ACLI) distributes the survey and provides PBGC with ''double blind'' data (*i.e.,* PBGC is unable to match responses with the insurance companies that submitted them). PBGC also uses the information from the surveys to determine the interest assumption it uses to value benefits payable to participants and beneficiaries in PBGC-trusteed plans for purposes of PBGC's financial statements.

PBGC intends to make conforming, clarifying, and editorial changes to the survey forms and instructions.

This voluntary survey is directed at insurance companies most, if not all, of which are members of ACLI. The survey is conducted quarterly and approximately 10 insurance companies will be asked to participate. PBGC estimates that about six insurance companies will respond to the survey each quarter, and that each survey will require approximately 30 minutes to complete and return. The total burden is estimated to be 12 hours (30 minutes per survey x four surveys per year x six respondents per quarter).

The existing collection of information was approved under OMB control number 1212–0030 (expires July 31, 2024). PBGC intends to request that OMB approve PBGC's use of this form for 3 years. 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.

PBGC is soliciting public comments to—

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodologies and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submission of responses.

Issued in Washington, DC by:

Hilary Duke,

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

[FR Doc. 2024–02072 Filed 2–1–24; 8:45 am]

BILLING CODE 7709–02–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–169 and CP2024–175]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 6, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://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

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each 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 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

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]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s)

[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).

that the Postal Service states concern Competitive product(s), 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 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–169 and CP2024–175; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 176 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* January 29, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Samuel Robinson; *Comments Due:* February 6, 2024.

This Notice will be published in the **Federal Register**.

Jennie L. Jbara,

Alternate Certifying Officer.

[FR Doc. 2024–02105 Filed 2–1–24; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99440; File No. SR–NYSEARCA–2024–10]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

January 29, 2024.

Pursuant to section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on January 25, 2024, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule (''Fee Schedule'') regarding the Floor Broker Fixed Cost Prepayment Incentive Program (the ''FB Prepay Program''). The Exchange proposes to implement the fee change effective January 25, 2024.[4] The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to modify the FB Prepay Program. The Exchange proposes to implement the rule change on January 25, 2024.

The FB Prepay Program is a prepayment incentive program that allows Floor Brokers to prepay certain of their annual Eligible Fixed Costs in exchange for volume rebates. Participating Floor Brokers receive their monthly rebate amount on a monthly basis.[5] All Floor Brokers that participate in the FB Prepay Program are eligible for a rebate on manual billable volume of ($0.08) per billable side, payable on a monthly basis. In addition, FB Prepay Program participants that achieve more than 500,000 billable sides in a month are eligible for an additional rebate of ($0.02) per billable side. The additional ($0.02) is retroactive to the first billable side. Manual billable volume includes transactions for which at least one side is subject to manual transaction fees and excludes QCCs. Any volume calculated to achieve the Limit of Fees on Options Strategy Executions (''Strategy Cap''), regardless of whether this cap is achieved, is likewise excluded from the Manual Billable Rebate Program because fees on such volume are already capped and therefore such volume does not increase billable manual volume. The Exchange notes that it places a $2,000,000 per firm, monthly maximum limit on the rebates earned through the Manual Billable Rebate Program when combined with ''Submitting Broker QCC Credits.'' [6]

Floor Brokers that wish to participate in the FB Prepay Program for the following calendar year must notify the Exchange no later than the last business day of December in the current year.[7] The Exchange does not issue any refunds in the event that a Floor Broker organization's prepaid Eligible Fixed Costs exceeds actual costs.

The Exchange proposes to modify the FB Prepay Program as follows. First, the Exchange proposes to increase the maximum allowable combined Submitting Broker QCC credits and Floor Broker rebates earned through the Manual Billable Rebate Program (the ''Maximum Combined Rebate/Credit'') to $2,500,000 per month per firm, an increase from the current maximum of $2,000,000. The proposed increase is designed to encourage Floor Broker firms to continue to direct transactions to the Exchange, despite increasing industry volumes making it less difficult to attain the maximum rebate.

Next, the Exchange proposes to modify the FB Prepay Program to

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed to amend the Fee Schedule on January 2, 2024 (NYSEArca–2023–90) [sic] and withdrew such filing on January 12, 2024 (SR–NYSEArca–2024–07) [sic], which latter filing the Exchange withdrew on January 25, 2024.

[5] *See* Fee Schedule, Floor Broker Fixed Cost Prepayment Incentive Program (the ''FB Prepay Program''). The Exchange notes that the FB Prepay Program is currently structured similarly to the Floor Broker prepayment program offered by its affiliated exchange, NYSE American LLC (''NYSE American'').

[6] *See* Fee Schedule, FB Prepay Program, endnote 17 (providing in relevant part that ''Submitting Broker QCC credits and Floor Broker rebates earned through the Manual Billable Rebate Program shall not combine to exceed $2,500,000 per month per firm''). A ''Submitting Broker QCC credit'' is available to any broker submitting a QCC transaction to the Exchange (a ''Submitting Broker''), whether the broker is a Floor Broker on the Trading Floor or a broker that enters orders electronically through an interface with the Exchange. The Exchange provides a ($0.22) per contract credits to Submitting Brokers for Non-Customer vs. Non-Customer QCC transactions and a ($0.16) per contract credit to Submitting Brokers for Customer vs. Non-Customer QCC transactions. *See* Fee Schedule, NYSE Arca OPTIONS: TRADE-RELATED CHARGES FOR STANDARD OPTIONS, QUALIFIED CONTINGENT CROSS (''QCC'') TRANSACTION FEES AND CREDITS.

[7] *See* Fee Schedule, FB Prepay Program (providing, in relevant part, that the notification ''email to enroll in the Program must originate from an officer of the Floor Broker organization and, *except as provided for below,* represents a binding commitment through the end of the following calendar year.''). The Exchange proposes to modify Section III.E. [sic] of the Fee Schedule to remove the now obsolete phrase ''except as provided for below,'' as there is no exception to the notification requirement, which modification will add clarity, transparency, and internal consistency to the Fee Schedule. *See* proposed Fee Schedule, FB Prepay Program.

remove reference to a specific year (*i.e.,* November 2022) and to instead reference ''November of the current year'' as the date that the Exchange will use for the calculation of a Floor Broker's Eligible Fixed Costs for the following calendar year. The FB Prepay Program currently specifies that a Floor Broker that commits to the program will be invoiced in January for Eligible Fixed Costs, based on annualizing their Eligible Fixed Costs incurred in November 2022. The Exchange believes that this proposed change would prevent the Exchange from relying on a stale date and would add flexibility to the program (insofar as it would not need to be revised each year).

Finally, the Exchange proposes to allow a Floor Broker to join the Program after the first of the year To do so, similar to the protocol required of existing Program participants, such Floor Broker organizations would notify the Exchange in writing by emailing *optionsbilling@nyse.com* and indicating their commitment to submit prepayment for the balance of the calendar year; the email notification would have to originate from an officer of the Floor Broker organization and would represent a binding commitment through the balance of the calendar year.[8] As further proposed, the Floor Broker organization would be enrolled in the Program beginning on the first day of the next full month and would be invoiced for that first full month for Eligible Fixed Costs and the balance of the year, based on annualizing for the remainder of the calendar year their Eligible Fixed Costs incurred in its first full month in the Program.[9] The Exchange notes that both the current and proposed methodology rely on recently incurred Eligible Fixed Costs to predict anticipated Eligible Fixed Costs. For current program Participants the Exchange relies on November costs; whereas, for later-joining Program participants, the Exchange would rely on costs incurred in the Floor Broker's first full month in the Program. The Exchange believes that this approach allows the Exchange the flexibility to offer the FB Prepay Program to Floor Brokers that did not enroll before the end of the prior calendar year, including/especially Floor Brokers new to the Exchange, without putting these Floor Brokers at a competitive disadvantage.

Although the Exchange cannot predict with certainty whether the proposed changes to the FB Prepay Program would encourage Floor Brokers to participate in the program or to increase their manual billable volume, the Exchange believes that the proposed changes would continue to incent Floor Brokers to participate in the FB Prepay Program by adding flexibility to the structure of the Program, including by allowing Floor Brokers to join the Program after the first of the year and increasing the Maximum Combined Rebate/Credit. All Floor Brokers are eligible to participate in the FB Prepay Program and qualify for the proposed rebates.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[10] in general, and furthers the objectives of sections 6(b)(4) and (5) of the Act,[11] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

There are currently 17 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[13] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in November 2023, the Exchange had less than 12% market share of executed volume of multiply-listed equity and ETF options trades.[14]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, modifications to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The Exchange believes that the proposed changes are reasonable because they are designed to continue to incent Floor Brokers to increase the number of manual transactions sent to the Exchange by offering them rebates on manual transactions with at least one billable side. The Exchange also believes that the proposed higher maximum monthly amount that a firm could earn from Submitting Broker QCC credits and Floor Broker rebates on manual billable volume (*i.e.,* the Maximum Combined Rebate/Credit) is reasonable because it is set at an amount that is designed to encourage Floor Brokers to direct QCC transactions and manual billable volume to the Exchange to receive the existing credits and proposed rebates.

With respect to the FB Prepay Program, the Exchange also believes that the proposed changes are reasonable because participation in the program is optional, and Floor Brokers can elect to participate in the program to be eligible for the rebates offered through the Manual Billable Rebate Program or not. The Exchange also believes that the proposed modification of the FB Prepay Program is reasonable because it is designed to continue to encourage Floor Brokers to participate in the FB Prepay Program, and to provide liquidity on the Exchange. Specifically, the Exchange

[8] *See* proposed Fee Schedule, FB Prepay Program (providing, in relevant part, that ''[t]o participate in the FB Prepay Program after the first of the year, Floor Broker organizations must notify the Exchange in writing by emailing *optionsbilling@nyse.com,* indicating a commitment to submit prepayment for the balance of the calendar year'' and that the notification ''email to enroll in the Program must originate from an officer of the Floor Broker organization and represents a binding commitment through the balance of the calendar year.'').

[9] *See* proposed Fee Schedule, FB Prepay Program.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[13] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[14] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.,* the Exchange's market share in equity-based options decreased from 12.31% for the month of November 2022 to 11.67% for the month of November 2023.

believes that the proposed continuation of the FB Prepay Program to offer participating Floor Brokers rebates on manual billable volume is reasonable because it would maintain both the incentives offered to Floor Brokers and the qualification basis for such incentives; all Floor Brokers participating in the FB Prepay Program would be eligible for the same rebate on manual billable volume and would qualify for the same additional rebate on manual billable volume by meeting a set volume threshold (which the Exchange believes is reasonable and is attainable based on manual billable volume rebates earned by Floor Brokers).

To the extent that the continued aspects of the program continue to attract more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution, which, in turn, promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system. The Exchange notes that all market participants stand to benefit from any increase in volume entered by Floor Brokers, which could promote market depth, facilitate tighter spreads, and enhance price discovery, to the extent the proposed change encourages Floor Brokers to utilize the Exchange as a primary trading venue, and may lead to a corresponding increase in order flow from other market participants. In addition, any increased liquidity on the Exchange would result in enhanced market quality for all participants.

The Exchange also believes that the proposed change to modify the Program to remove reference to a specific year is reasonable because it would prevent the Exchange from using a benchmark based on a stale date and would add flexibility to the Program (insofar as it would not need to be revised each year). In addition, the proposed change to allow Floor Brokers to join the Program after the first of the year—by prepaying an amount (to cover the balance of the year) based on their Eligible Fixed Costs incurred in their first month in the Program—is reasonable for several reasons. First, the proposed method used to determine the prepayment amount for any later-joining Floor Brokers is analogous to the Exchange's current method of determining the prepayment amount for Program participants (*i.e.,* prepayment amount is based on the Eligible Fixed Costs recently-incurred). Second, the Exchange believes that the proposed method of determining a (later-joining) Floor Broker's prepayment amount would provide the most accurate basis for anticipating that Floor Broker's future Eligible Fixed Costs. Moreover, the Exchange believes that this approach would allow the Exchange the flexibility to offer the FB Prepay Program to later-joining Floor Brokers, including/especially Floor Brokers new to the Exchange, without putting these Floor Brokers at a competitive disadvantage.

To the extent the continuation of the program would continue to attract greater volume and liquidity, the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The Exchange's fees are constrained by intermarket competition, as Floor Brokers may direct their order flow to any of the 17 options exchanges, including an exchange offering Floor Broker rebates on manual transactions.[15] Thus, Floor Brokers have a choice of where they direct their order flow, including their manual transactions. The proposed rule changes are designed to continue to incent Floor Brokers to direct liquidity and, in particular, manual transactions to the Exchange. In addition, to the extent Floor Brokers are incented to continue to aggregate their trading activity at the Exchange, that increased liquidity could promote market depth, price discovery and improvement, and enhanced order execution opportunities for market participants.

Finally, the proposed changes to remove superfluous or obsolete text from the FB Prepay Program, are reasonable because they would add clarity, transparency, and internal consistency to the Fee Schedule to the benefit of all market participants.

The Proposed Rule Change Is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits because the proposal is based on the amount and type of business transacted on the Exchange. Floor Brokers are not obligated to participate in the FB Prepay Program, and those who do can choose to execute manual billable volume to earn rebates through the Manual Billable Rebate Program or not. In addition, the Manual Billable Rebate Program continues to be equally available to all Floor Brokers that participate in the FB Prepay Program and the proposed monthly limit on the amount that firms could earn from Floor Broker manual billable rebates and Submitting Broker QCC credits combined would apply to all firms equally (*i.e.,* the Maximum Combined Rebate/Credit).

The Exchange also notes that the proposed changes are designed to encourage Floor Brokers that have previously enrolled in the FB Prepay Program to reenroll for the upcoming year, as well as to attract Floor Brokers that have not yet participated in the program. Moreover, the Exchange believes that the proposed modifications to the FB Prepay Program are an equitable allocation of fees and credits because they would apply to participating Floor Brokers equally and are intended to encourage the role performed by Floor Brokers in facilitating the execution of orders via open outcry, a function which the Exchange wishes to support for the benefit of all market participants.

The Exchange also believes that the proposed change to modify the Program to remove reference to a specific year is equitable because it would prevent the Exchange from using a benchmark based on a stale date. In addition, the proposed change to allow Floor Brokers to join the Program after the first of the year—by prepaying an amount (to cover the balance of the year) based on their Eligible Fixed Costs incurred in their first month in the Program—is equitable for several reasons. First, the proposed method used to determine the prepayment amount for any later-joining Floor Brokers is analogous to the Exchange's current method of determining the prepayment amount for Program participants (*i.e.,* prepayment amount is based on the Eligible Fixed Costs recently-incurred). Second, the Exchange believes that the proposed method of determining a (later-joining) Floor Broker's prepayment amount would provide the most accurate basis for anticipating that Floor Broker's future Eligible Fixed Costs. Moreover, the Exchange believes that this approach would allow the Exchange the flexibility to offer the FB Prepay Program to later-joining Floor Brokers, including/especially Floor Brokers new to the Exchange, without putting these Floor Brokers at a competitive disadvantage.

Moreover, the proposed changes are designed to continue to incent Floor Brokers to encourage OTP Holders to aggregate their executions at the Exchange as a primary execution venue.

[15] *See id.*

To the extent that the proposed change achieves its purpose in attracting more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes the proposed change is not unfairly discriminatory because it is based on the amount and type of business transacted on the Exchange. Floor Brokers are not obligated to execute manual billable transactions or participate in the FB Prepay Program, and the proposed rebates offered through the Manual Billable Rebate Program are available to all Floor Brokers that participate in the FB Prepay Program on a non-discriminatory basis. The proposed changes are designed to add flexibility to the FB Prepay Program by offering all participating Floor Brokers the same increased Maximum Combined Rebate/Credit and to encourage Floor Brokers to utilize the Exchange as a primary trading venue for all transactions (if they have not done so previously) and increase manual billable volume sent to the Exchange.

The Exchange also believes that the proposed change to modify the Program to remove reference to a specific year is not unfairly discriminatory because it would apply equally to all Program participants and would prevent the Exchange from using a benchmark based on a stale date. In addition, the proposed change to allow Floor Brokers to join the Program after the first of the year—by prepaying an amount (to cover the balance of the year) based on their Eligible Fixed Costs incurred in their first month in the Program—is not unfairly discriminatory for several reasons. First, the proposed method used to determine the prepayment amount for any later-joining Floor Brokers is analogous to the Exchange's current method of determining the prepayment amount for Program participants (*i.e.,* prepayment amount is based on the Eligible Fixed Costs recently-incurred). Second, the Exchange believes that the proposed method of determining a (later-joining) Floor Broker's prepayment amount would provide the most accurate basis for anticipating that Floor Broker's future Eligible Fixed Costs. Moreover, the Exchange believes that this approach would allow the Exchange the flexibility to offer the FB Prepay Program to later-joining Floor Brokers, including/especially Floor Brokers new to the Exchange, without putting these Floor Brokers at a competitive disadvantage.

To the extent that the proposed continuation of (and modifications to) the Program attracts more manual transactions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [16]

Intramarket Competition. The continuation of the rebates on manual billable volume is designed to attract additional order flow to the Exchange (particularly in manual billable transactions), which could increase the volumes of contracts traded on the Exchange. The proposed modification of the FB Prepay Program is likewise intended to incent Floor Brokers specifically to direct manual billable transactions to the Exchange, as well as encourage Floor Brokers to participate in the Program. The continued rebates would be available to all similarly situated Floor Brokers that participate in the FB Prepay Program. Greater liquidity benefits all market participants on the Exchange, and increased manual transactions could increase opportunities for execution of other trading interest. The proposed Maximum Combined Rebate/Credit would likewise apply equally to all similarly situated Floor Brokers.

To the extent that the proposed continuation of the program imposes an additional competitive burden on non-Floor Brokers, the Exchange believes that any such burden would be appropriate because all market participants stand to benefit from any increase in volume entered by Floor Brokers because an increase in trading volume could promote market depth, facilitate tighter spreads, and enhance price discovery. In addition, any increased liquidity on the Exchange would result in enhanced market quality for all participants.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 17 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[17] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in November 2023, the Exchange had less than 12% market

[16] *See* Reg NMS Adopting Release, *supra* note 12, at 37499.

[17] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

share of executed volume of multiply-listed equity and ETF options trades.[18]

The Exchange believes that the proposed changes reflect this competitive environment because they modify the Exchange's fees and rebates in a manner designed to continue to incent OTP Holders to direct trading interest (particularly manual transactions) to the Exchange, to provide liquidity and to attract order flow. To the extent that Floor Brokers are encouraged to participate in the FB Prepay Program and/or incented to utilize the Exchange as a primary trading venue for all transactions, all of the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

The Exchange further believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer rebates on manual transactions by encouraging additional orders to be sent to the Exchange for execution.

Finally, the proposed changes to remove superfluous or obsolete text from the FB Prepay Program are not designed to address any competitive issue but are instead designed to add clarity, transparency, and internal consistency to the Fee Schedule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to section 19(b)(3)(A)[19] of the Act and subparagraph (f)(2) of Rule 19b–4[20] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B)[21] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEARCA–2024–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2024–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2024–10 and should be submitted on or before February 23, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–02062 Filed 2–1–24; 8:45 am]

BILLING CODE 8011–01–P

[18] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.,* the Exchange's market share in equity-based options decreased from 12.31% for the month of November 2022 to 11.67% for the month of November 2023.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(2).

[21] 15 U.S.C. 78s(b)(2)(B).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99444; File No. SR–MSRB–2023–06]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Suspension of and Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Establish the 2024 Rate Card Fees for Dealers and Municipal Advisors Pursuant to MSRB Rules A–11 and A–13

January 29, 2024.

I. Introduction

On November 30, 2023, the Municipal Securities Rulemaking Board (''MSRB'' or ''Board'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change (File No. SR–MSRB–2023–06) to establish the 2024 Rate Card Fees for Dealers and Municipal Advisors.[3] The proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[4] The proposed rule change was published for comment in the **Federal Register** on December 12, 2023.[5] Pursuant to Section 19(b)(3)(C) of the Act,[6] the Commission is hereby temporarily suspending File No. SR–MSRB–2023–06 and instituting

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–99096 (December 6, 2023), 88 FR 86188 (December 12, 2023) (''Notice'').

[4] 15 U.S.C. 78s(b)(3)(A). A proposed rule change may take effect upon filing with the Commission if it is designated by the SRO as ''establishing or changing a due, fee, or other charge imposed by the self-regulatory organization on any person, whether or not the person is a member of the self-regulatory organization.'' 15 U.S.C. 78s(b)(3)(A)(ii).

[5] *See* Notice 88 FR at 86188.

[6] 15 U.S.C. 78s(b)(3)(C).

proceedings to determine whether to approve or disapprove File No. SR–MSRB–2023–06.

II. Description of the Proposed Rule Change

The MSRB filed with the Commission the proposed rule change to amend, consistent with the MSRB's annual rate-setting process (''Annual Rate Card Process''):[7] (i) Supplementary Material .01 to Rule A–11 to modify the rate of assessment for the annual rate card fees on municipal advisors for covered professionals under Rule A–11(b) (the ''Municipal Advisor Professional Fee''); and (ii) Supplementary Material .01 to Rule A–13 to modify the rate of assessments for the annual rate card fees on brokers, dealers, and municipal securities dealers (collectively, ''dealers'') for certain underwriting fees under Rule A–13(b), transaction fees under Rule A–13(d)(i) and (ii), and trade count fees under Rule A–13(d)(iv)(a) and (b) (collectively, the ''Market Activity Fees'' and, together with the Municipal Advisor Professional Fee, the ''Rate Card Fees'').[8]

In July 2023, the board of directors of the MSRB approved an annual expense budget of approximately $47.4 million for Fiscal Year 2024, which represents a 4.8% increase over the prior fiscal year, and established the baseline revenue that the MSRB will need to operate (*i.e.,* the ''Operational Funding Level'').[9] To achieve this Operational Funding Level, the MSRB proposed Rate Card Fees in its proposed rule change allocated based on the following contribution targets: underwriting fee at 30%; transaction fee at 41%; trade count fee at 21%; and Municipal Advisor Professional Fee at 8%.[10] This resulted in Proportional Contribution Amounts as follows for Fiscal Year 2024: underwriting fee of $12.15 million; transaction fee of $16.61 million; trade count fee of $8.51 million; and Municipal Advisor Professional Fee of $3.24 million.[11] The proposed rule change would establish the Municipal Advisor Professional Fee specified in Rule A–11 and the Market Activity Fees specified in Rule A–13 in accordance with the chart below.[12]

	Basis	Current rate for 2023	Proposed rate for 2024
Underwriting Fee	Per $1,000 Par Underwritten	$0.0297	$0.0371
Transaction Fee	Per $1,000 Par Transacted	0.0107	0.0091
Trade Count Fee	Per Trade	1.10	0.57
Municipal Advisor Professional Fee	Per Covered Professional	1,060	1,160

The MSRB designated the proposed rule change for immediate effectiveness.[13] The new Rate Card Fees reflected in the proposed rule change became effective as of January 1, 2024.[14]

III. Summary of Comments Received to the Proposed Rule Change

The Commission received four comment letters [15] on the proposed rule change during the comment period. The Commission's Office of Municipal Securities also held a meeting with representatives of the American Securities Association (''ASA''), Bond Dealers of America (''BDA''), National Association of Municipal Advisors (''NAMA''), and the Securities Industry and Financial Markets Association (''SIFMA'' and, collectively with ASA, BDA, and NAMA, the ''Joint Commenters'').[16] The Commission received an additional, supplemental comment letter from SIFMA and BDA after the comment period had ended.[17] On January 26, 2024, the MSRB responded to the comment letters.[18]

The Joint Commenters expressed concern with the proposed rule change.[19] Among other things, the Joint Commenters expressed concern ''about the lack of transparency in the Municipal Securities Rulemaking Board's budget and its budgeting process, and the need for MSRB's resources to be directed toward areas within its statutory authority.'' [20] The Joint Commenters described the MSRB's budgeting and rate-setting strategy as ''alarmingly opaque and troubling'' and lacking detail, particularly in instances where expenses are not directly tied to projects aligned with its congressional mandate.[21] For example, the Joint Commenters cited a portion of the

[7] *See* Notice 88 FR at 86188. *See also* Exchange Act Release No. 95417 (Aug. 3, 2022), 87 FR 48530 (Aug. 9, 2022), File No. SR–MSRB–2022–06 (establishing the MSRB's Annual Rate Card Process with respect to the setting of certain fee rates each calendar year (an ''Annual Rate Card'') and setting the initial Rate Card Fees through December 31, 2023) (the ''Annual Rate Card Process Notice'').

[8] *See* Notice 88 FR at 86188. The proposed amendments to Supplementary Material .01 to Rule A–11 and Supplementary Material .01 to Rule A–13 collectively make up the ''proposed rule change.''

[9] *See* Notice 88 FR at 86188; MSRB Fiscal Year 2024 Budget, available at *https://www.msrb.org/sites/default/files/2023-09/MSRB-FY-2024-Budget-Summary.pdf.*

[10] *See* Notice 88 FR at 86189.

[11] *Id.* According to the MSRB, these contribution targets were determined by averaging the distribution of revenue assessed for Rate Card Fees over the past two fiscal years (Fiscal Year 2022 and Fiscal Year 2023) and the distribution of revenue assessed for Rate Card Fees over the past five fiscal years (Fiscal Year 2019 through Fiscal Year 2023). These two periods of time were used to reflect a balance of current market conditions and a longer-term historical precedent. To make the data comparable across fiscal years, the calculations were completed using the Market Activity Fee rates that were in place prior to the 2023 Rate Card, excluding the impact of the temporary fee reductions, and calculated as if the Municipal Advisor Professional Fee rate of $1,000 per covered professional that was in place for Fiscal Years 2021 and 2022 had been in place for all Fiscal Years used in the calculations. Resulting contribution targets were rounded to the nearest whole percent. *See also* MSRB Fiscal Year 2024 Budget, available at *https://www.msrb.org/sites/default/files/2023-09/MSRB-FY-2024-Budget-Summary.pdf.*

[12] *See* Notice 88 FR at 86190.

[13] *Id.* at 86188.

[14] *Id.*

[15] *See* Letter from Leslie M. Norwood, Managing Director, Associate General Counsel, Securities Industry and Financial Markets Association, dated January 2, 2024 (''SIFMA Letter''); Letter from Susan Gaffney, Executive Director, National Association of Municipal Advisors, dated January 2, 2024 (''NAMA Letter''); Letter from Michael Decker, Senior Vice President, Research and Public Policy, Bond Dealers of America, dated January 2, 2024 (''BDA Letter''); Letter from Jessica Giroux, General Counsel and Head of Fixed Income Policy, American Securities Association; Michael Decker, Senior Vice President for Research and Public Policy, Bond Dealers of America; Susan Gaffney, Executive Director, National Association of Municipal Advisors; and Leslie Norwood, Managing Director, Associate General Counsel, and Head of Municipal Securities, Securities and Financial Markets Association, dated January 2, 2024 (''Joint Letter'').

[16] *See* Memorandum from the Office of Municipal Securities regarding a December 11, 2023 meeting with representatives of the American Securities Association (ASA), Bond Dealers of America (BDA), National Association of Municipal Advisors (NAMA), and Securities Industry and Financial Markets Association (SIFMA), dated December 11, 2023 (''OMS Memo'').

[17] *See* Letter from Michael Decker, Senior Vice President, Bond Dealers of America and Leslie Norwood, Managing Director and Associate General Counsel, Securities and Financial Markets Association, dated January 24, 2024 (''Supplemental Letter'').

[18] *See* Letter from Ernesto A. Lanza, Chief Regulatory and Policy Officer, Municipal Securities Rulemaking Board, dated January 26, 2024 (''MSRB Letter'').

[19] Joint Letter at 1–2.

[20] *Id.* at 1.

[21] *Id.*

MSRB's budget that highlights technology initiatives, but that lacks specificity regarding those initiatives, including their costs and their alignment with the MSRB's role as a repository for disclosure documents.[22] Without such information, it is difficult, the Joint Commenters believe, for regulated entities to assess whether the fees assessed in the proposed rule change are ''reasonable'' as required under the Exchange Act.[23]

BDA expressed concern over the MSRB's approach to fee setting, and believes that the Board's budget process is opaque with little to no outside oversight over the MSRB's spending.[24] BDA stated that it would like to see the MSRB provide more transparency into its budgeting process and setting budget priorities, particularly regarding the MSRB's focus on IT development and maintenance, which comprises 56 percent of the MSRB budget.[25] BDA is also concerned that the MSRB has provided no justification in its proposed rule change for imposing fee increases that BDA believes impose a ''heavy'' burden on dealers.[26]

NAMA expressed concern with the MSRB's approach to budgeting and rate setting to accommodate its budget.[27] In particular, NAMA noted that ''it is difficult to know if MSRB fees are set at a reasonable rate (a MSRB responsibility within SEC Rule 15B) when the MSRB's budget is so opaque.'' [28] As one example, NAMA cited the lack of cost information and sufficient detail in the MSRB's budget to demonstrate whether its emphasis on technology systems supports its congressional mandate.[29] NAMA believes there is ''insufficient detail within the budget to allow regulated parties (who pay for these activities) the opportunity to appropriately evaluate, address or question the fees assessed to meet the MSRB's budget needs.'' [30]

SIFMA expressed concern that the proposed rule change does not provide adequate transparency on the MSRB's rate setting process, reflects significant fee volatility, and fails to address flaws in the rate setting process that could create market harms.[31] Regarding fee volatility, SIFMA noted that the underwriting fee has been increased 25% and the trade count fee reduced by 48%, yet the MSRB failed to explain why it believes this volatility in fee rates will not be repeated in subsequent years.[32] Regarding transparency, SIFMA expressed concern that the MSRB's proposed rule change includes ''significant and material changes'' to its fee structure, yet the MSRB gave regulated entities its first official description of the amount of those changes a mere three weeks before they became effective.[33] Regarding market harms, SIFMA noted that the MSRB is proposing to increase underwriting fees even as new issuance has decreased this past year, which could hurt the viability of the municipal marketplace.[34]

In their Supplemental Letter, SIFMA and BDA argued that although they have raised concerns about the MSRB's budgeting and fee setting processes, the Commission should allow the proposed rule change to take effect without any changes.[35] SIFMA and BDA expressed concern that suspending the proposed rule change could be ''operationally disruptive'' for dealers and would leave transactional fees ''in limbo'' until a 2024 Rate Card is approved.[36] SIFMA and BDA noted that they have had preliminary conversations with the MSRB about its budget and fee setting processes and will continue to press the MSRB as it works on its 2025 Budget.[37]

The MSRB argued that its 2024 Budget ''provides sufficient basis to evaluate the reasonableness of the 2024 Rate Card Fees'' and urged the Commission not to suspend the proposed rule change.[38] The MSRB also outlined its plan for an ongoing process of ''engagement'' which would include: (i) a retrospective review of the Rate Card Process; (ii) instituting certain financial transparency enhancements, including more granular details regarding key technology services and initiatives; and (iii) developing avenues to provide municipal market participants an opportunity to offer input to the MSRB in advance of finalization of annual budgets.[39]

The MSRB stated that its retrospective review of the Rate Card Process will consider the appropriateness of instituting caps on fee changes more broadly or other means to limit the magnitude of year-to-year fee changes.[40] The retrospective review also ''could reconsider'' a revenue-based or transaction volume-based fee assessment model.[41]

Regarding financial transparency, the MSRB cited Section IV of its 2024 Budget Summary as an example of its ''granular breakdown'' of program expenditures and stated that it will seek feedback on whether this ''additional information'' is responsive to commenters' requests for greater detail about the MSRB's budget areas and initiatives.[42] The MSRB stated that it would develop ''reasonable allocation assumptions'' to aid in the understanding of its technology system-related expenses.[43] The MSRB also stated that it will ''explore other possible avenues'' for improving the transparency of its technology initiatives and priorities and believes that all such expenditures are within the MSRB's legal authority.[44]

Regarding input from market participants, the MSRB stated that it ''looks to provide'' opportunities for market participants to provide input and ''could consider'' a more formalized survey of market participants during the rate setting process.[45]

IV. Suspension of the Proposed Rule Change

Pursuant to Section 19(b)(3)(C) of the Act,[46] at any time within 60 days of the date of filing of an immediately effective proposed rule change pursuant to Section 19(b)(1) of the Act,[47] the Commission summarily may temporarily suspend the change in the rules of a self-regulatory organization (''SRO'') 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. As described below, the Commission believes a temporary suspension of the proposed rule change is necessary or appropriate to allow for additional analysis of the proposed rule change's consistency with the Act and the rules thereunder.

When SROs file their proposed rule changes with the Commission, including fee filings like the MSRB's present proposed rule change, they are required to provide a statement supporting the proposed rule change's basis under the Act and the rules and regulations thereunder applicable to the

[22] *Id.*
[23] *Id.*
[24] BDA Letter at 1.
[25] *Id.* at 2–3.
[26] *Id.* at 1–2.
[27] NAMA Letter at 1–2.
[28] *Id.* at 1.
[29] *Id.* at 1–2.
[30] *Id.* at 2.
[31] SIFMA Letter at 1.
[32] *Id.* at 2.
[33] *Id.* at 3.
[34] *Id.* at 4.
[35] Supplemental Letter at 1.
[36] *Id.*
[37] *Id.*
[38] MSRB Letter at 10.
[39] *Id.* at 1–2.
[40] *Id.* at 3–4.
[41] *Id.* at 4–5.
[42] *Id.* at 5–6.
[43] *Id.* at 6–7.
[44] *Id.* at 7–8.
[45] *Id.* at 8–9.
[46] 15 U.S.C. 78s(b)(3)(C).
[47] 15 U.S.C. 78s(b)(1).

SRO.[48] The instructions to Form 19b–4, on which SROs file their proposed rule changes, specify that such statement ''should be sufficiently detailed and specific to support a finding that the proposed rule change is consistent with [those] requirements.'' [49]

Among other things, the MSRB's proposed rule change is subject to Section 15B(b)(2)(J) of the Exchange Act,[50] which states that the MSRB's rules shall provide that each municipal securities broker, municipal securities dealer, and municipal advisor shall pay to the MSRB such reasonable fees and charges as may be necessary or appropriate to defray the costs and expenses of operating and administering the MSRB.[51] Such rules must specify the amount of such fees and charges, which may include charges for failure to submit to the MSRB, or to any information system operated by the MSRB, within the prescribed timeframes, any items of information or documents required to be submitted under any rule issued by the MSRB.[52] The MSRB's proposed rule change also is subject to Section 15B(b)(2)(C) of the Exchange Act,[53] which states, among other things, that the MSRB's rules shall be designed, in general, to protect investors, municipal entities, obligated persons, and the public interest.

In support of its proposed rule change, the MSRB stated that the proposed rule change satisfies the requirements of Section 15B(b)(2)(J) ''through a reasonable fee structure that ensures (i) an equitable balance of necessary and appropriate fees among regulated entities and (ii) a fair allocation of the burden of defraying the costs and expenses of the MSRB.'' [54] Specifically, the MSRB believes that the 2024 Rate Card ''will achieve reasonable fees to be paid by regulated entities that (i) are necessary and appropriate to sustain the operation and administration of the MSRB by defraying the MSRB's anticipated Fiscal Year 2024 operating and administrative expenses; (ii) reasonably and appropriately allocate fees among firms by equitably distributing fees in accordance with each individual firm's overall market activities; and (iii) reasonably and appropriately adjust for the annual fluctuations in the volume of market activity as compared to budget expectation by incorporating the actual amounts of Market Activity Fees and Municipal Advisor Professional Fees collected as compared to budget into this and future rate-setting processes.'' [55] The MSRB provided additional support for the reasonableness of the proposed rule change in the MSRB Letter.[56] However, due to the date of receipt of the MSRB Letter (*i.e.,* late afternoon one business day before the suspension deadline), the Commission has not had sufficient time to evaluate the material included therein. Temporary suspension will allow for additional analysis of whether the MSRB Fiscal Year 2024 Budget is reasonable and whether the proposed rule change provides for reasonable fees and charges that satisfy the standards under the Act and the rules thereunder.

In temporarily suspending the MSRB's proposed rule change, the Commission intends to further consider whether the proposed fees and charges are consistent with the statutory requirements applicable to the MSRB under the Act. Among other things, the Commission will consider whether the proposed rule change provides for reasonable fees and charges that satisfy the standards under the Act and the rules thereunder.[57] The Commission will also consider whether the fees and charges in the proposed rule change are necessary or appropriate to defray the costs and expenses of operating and administering the MSRB,[58] including whether such costs and expenses, as set forth in the MSRB's Fiscal Year 2024 Budget, are themselves reasonable. Additionally, the Commission will consider whether the fees and charges in the proposed rule change are in the public interest.[59]

Therefore, the Commission finds that it is necessary or appropriate in the public interest, for the protection of investors, and otherwise in furtherance of the purposes of the Act, to temporarily suspend the proposed rule change.[60]

V. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Change

In addition to temporarily suspending the proposal, the Commission also hereby institutes proceedings pursuant to Sections 19(b)(3)(C) [61] and 19(b)(2)(B) [62] of the Act to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change to inform the Commission's analysis of whether to approve or disapprove the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[63] the Commission is providing notice of the grounds for possible disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of whether the MSRB has sufficiently demonstrated how the proposed rule change is consistent with Sections 15B(b)(2)(J) and 15B(b)(2)(C) of the Act.[64] Section 15B(b)(2)(J) of the Act states that the MSRB's rules shall provide that each municipal securities broker, municipal securities dealer, and municipal advisor shall pay to the MSRB such reasonable fees and charges as may be necessary or appropriate to defray the costs and expenses of operating and administering the MSRB.[65] Such rules must specify the amount of such fees and charges, which may include charges for failure to submit to the MSRB, or to any information system operated by the MSRB, within the prescribed timeframes, any items of information or documents required to be submitted under any rule issued by the MSRB.[66] Section 15B(b)(2)(C) of the Exchange Act [67] states, among other things, that

[48] *See* 17 CFR 240.19b–4 (Item 3 entitled ''Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change'').

[49] *See id.*

[50] 15 U.S.C. 78o–4(b)(2)(J).

[51] *Id.*

[52] *Id.*

[53] 15 U.S.C. 78o–4(b)(2)(C).

[54] Notice 88 FR at 86191.

[55] *Id.*

[56] MSRB Letter.

[57] 15 U.S.C. 78o–4(b)(2)(J).

[58] *Id.*

[59] 15 U.S.C. 78o–4(b)(2)(C).

[60] For purposes of temporarily suspending the proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[61] 15 U.S.C. 78s(b)(3)(C). Once the Commission temporarily suspends a proposed rule change, Section 19(b)(3)(C) of the Act requires that the Commission institute proceedings under Section 19(b)(2)(B) to determine whether a proposed rule change should be approved or disapproved.

[62] 15 U.S.C. 78s(b)(2)(B).

[63] 15 U.S.C. 78s(b)(2)(B). Section 19(b)(2)(B) of the Act also provides that proceedings to determine whether to disapprove a proposed rule change must be concluded within 180 days of the date of publication of notice of the filing of the proposed rule change. *See id.* The time for conclusion of the proceedings may be extended for up to 60 days if the Commission finds good cause for such extension and publishes its reasons for so finding, or if the SRO consents to the longer period. *See id.*

[64] 15 U.S.C. 78o–4(b)(2)(J).

[65] *Id.*

[66] *Id.*

[67] 15 U.S.C. 78o–4(b)(2)(C).

the MSRB's rules shall be designed, in general, to protect investors, municipal entities, obligated persons, and the public interest.

As discussed in Section IV above, the Notice, and the MSRB Letter, the MSRB has made various arguments in support of the proposals, and the Commission received comment letters disputing the MSRB's arguments and expressing concerns regarding the proposals.[68] In particular, commenters argued that the MSRB did not provide sufficient information to establish that the proposed fees and charges are consistent with the Act and the rules thereunder.[69]

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the [Act] and the rules and regulations issued thereunder . . . is on the [SRO] that proposed the rule change.'' [70] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[71] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations.[72] Moreover, ''unquestioning reliance'' on an SRO's representations in a proposed rule change would not be sufficient to justify Commission approval of a proposed rule change.[73]

The Commission believes it is appropriate to institute proceedings to allow for additional consideration and comment on the issues raised herein, including as to whether the proposed fees and charges are consistent with the Act, any potential comments or supplemental information provided by the MSRB, and any additional independent analysis by the Commission.

V. Commission's Solicitation of Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the concerns and issues identified above, as well as any other relevant concerns. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 15B(b)(2)(J), Section 15B(b)(2)(C), or any other provision of the Act, or the rules and regulations thereunder. The Commission asks that commenters address the sufficiency and merit of the MSRB's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change. The Commission also invites the written views of interested persons on: (i) what process the MSRB should undertake to ensure that the fees assessed in its Rate Card filing and underlying Budget are both reasonable and capable of meaningful evaluation by the public, market participants, and the Commission; (ii) what specific data and information the MSRB should publicly disclose (that it does not currently publicly disclose); (iii) when the MSRB should file its Rate Card each year; (iv) whether the MSRB's representations about the cost, functionality, and evolution of the EMMA system have been consistent with actual practice in the years since EMMA was adopted; and (v) what general steps could be taken in the future to minimize the potential operational disruption caused by either the Commission suspending a Rate Card filing or a Rate Card otherwise not being effective on January 1 of the calendar year. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[74]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by February 23, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by March 8, 2024.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MSRB–2023–06 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–MSRB–2023–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. 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–MSRB–2023–06 and should be submitted on or before February 23, 2024. Rebuttal comments should be submitted by March 8, 2024.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(3)(C) of the Act,[75] that File No. SR–MSRB–2023–06 be, and hereby is, temporarily suspended. In addition, the Commission is instituting proceedings to determine whether the proposed rule change should be approved or disapproved.

[68] *See supra* note 15.

[69] *See* discussion *supra* Section III.

[70] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[71] *See id.*

[72] *See id.*

[73] *See Susquehanna Int'l Group, LLP* v. *Securities and Exchange Commission,* 866 F.3d 442, 446–47 (D.C. Cir. 2017) (rejecting the Commission's reliance on an SRO's own determinations without sufficient evidence of the basis for such determinations).

[74] Section 19(b)(2) of the Exchange Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[75] 15 U.S.C. 78s(b)(3)(C).

For the Commission, pursuant to delegated authority.[76]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–02069 Filed 2–1–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99440; File No. SR–NYSEARCA–2024–10]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

January 29, 2024.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on January 25, 2024, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule (''Fee Schedule'') regarding the Floor Broker Fixed Cost Prepayment Incentive Program (the ''FB Prepay Program''). The Exchange proposes to implement the fee change effective January 25, 2024.[4] The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to modify the FB Prepay Program. The Exchange proposes to implement the rule change on January 25, 2024.

The FB Prepay Program is a prepayment incentive program that allows Floor Brokers to prepay certain of their annual Eligible Fixed Costs in exchange for volume rebates. Participating Floor Brokers receive their monthly rebate amount on a monthly basis.[5] All Floor Brokers that participate in the FB Prepay Program are eligible for a rebate on manual billable volume of ($0.08) per billable side, payable on a monthly basis. In addition, FB Prepay Program participants that achieve more than 500,000 billable sides in a month are eligible for an additional rebate of ($0.02) per billable side. The additional ($0.02) is retroactive to the first billable side. Manual billable volume includes transactions for which at least one side is subject to manual transaction fees and excludes QCCs. Any volume calculated to achieve the Limit of Fees on Options Strategy Executions (''Strategy Cap''), regardless of whether this cap is achieved, is likewise excluded from the Manual Billable Rebate Program because fees on such volume are already capped and therefore such volume does not increase billable manual volume. The Exchange notes that it places a $2,000,000 per firm, monthly maximum limit on the rebates earned through the Manual Billable Rebate Program when combined with ''Submitting Broker QCC Credits.''[6]

Floor Brokers that wish to participate in the FB Prepay Program for the following calendar year must notify the Exchange no later than the last business day of December in the current year.[7] The Exchange does not issue any refunds in the event that a Floor Broker organization's prepaid Eligible Fixed Costs exceeds actual costs.

The Exchange proposes to modify the FB Prepay Program as follows. First, the Exchange proposes to increase the maximum allowable combined Submitting Broker QCC credits and Floor Broker rebates earned through the Manual Billable Rebate Program (the ''Maximum Combined Rebate/Credit'') to $2,500,000 per month per firm, an increase from the current maximum of $2,000,000. The proposed increase is designed to encourage Floor Broker firms to continue to direct transactions to the Exchange, despite increasing industry volumes making it less difficult to attain the maximum rebate.

Next, the Exchange proposes to modify the FB Prepay Program to remove reference to a specific year (*i.e.,* November 2022) and to instead reference ''November of the current year'' as the date that the Exchange will use for the calculation of a Floor Broker's Eligible Fixed Costs for the following calendar year. The FB Prepay Program currently specifies that a Floor Broker that commits to the program will be invoiced in January for Eligible Fixed Costs, based on annualizing their Eligible Fixed Costs incurred in November 2022. The Exchange believes that this proposed change would prevent the Exchange from relying on a stale date and would add flexibility to the program (insofar as it would not need to be revised each year).

Finally, the Exchange proposes to allow a Floor Broker to join the Program after the first of the year To do so,

[76] 17 CFR 200.30–3(a)(11) and (12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed to amend the Fee Schedule on January 2, 2024 (NYSEArca–2023–90) [sic] and withdrew such filing on January 12, 2024 (SR–NYSEArca–2024–07) [sic], which latter filing the Exchange withdrew on January 25, 2024.

[5] *See* Fee Schedule, Floor Broker Fixed Cost Prepayment Incentive Program (the ''FB Prepay Program''). The Exchange notes that the FB Prepay Program is currently structured similarly to the Floor Broker prepayment program offered by its affiliated exchange, NYSE American LLC (''NYSE American'').

[6] *See* Fee Schedule, FB Prepay Program, endnote 17 (providing in relevant part that ''Submitting Broker QCC credits and Floor Broker rebates earned through the Manual Billable Rebate Program shall not combine to exceed $2,500,000 per month per firm''). A ''Submitting Broker QCC credit'' is available to any broker submitting a QCC transaction to the Exchange (a ''Submitting Broker''), whether the broker is a Floor Broker on the Trading Floor or a broker that enters orders electronically through an interface with the Exchange. The Exchange provides a ($0.22) per contract credits to Submitting Brokers for Non-Customer vs.Non-Customer QCC transactions and a ($0.16) per contract credit to Submitting Brokers for Customer vs. Non-Customer QCC transactions. *See* Fee Schedule, NYSE Arca OPTIONS: TRADE-RELATED CHARGES FOR STANDARD OPTIONS, QUALIFIED CONTINGENT CROSS (''QCC'') TRANSACTION FEES AND CREDITS.

[7] *See* Fee Schedule, FB Prepay Program (providing, in relevant part, that the notification ''email to enroll in the Program must originate from an officer of the Floor Broker organization and, *except as provided for below,* represents a binding commitment through the end of the following calendar year.''). The Exchange proposes to modify Section III.E. [sic] of the Fee Schedule to remove the now obsolete phrase ''except as provided for below,'' as there is no exception to the notification requirement, which modification will add clarity, transparency, and internal consistency to the Fee Schedule. *See* proposed Fee Schedule, FB Prepay Program.

similar to the protocol required of existing Program participants, such Floor Broker organizations would notify the Exchange in writing by emailing *optionsbilling@nyse.com* and indicating their commitment to submit prepayment for the balance of the calendar year; the email notification would have to originate from an officer of the Floor Broker organization and would represent a binding commitment through the balance of the calendar year.[8] As further proposed, the Floor Broker organization would be enrolled in the Program beginning on the first day of the next full month and would be invoiced for that first full month for Eligible Fixed Costs and the balance of the year, based on annualizing for the remainder of the calendar year their Eligible Fixed Costs incurred in its first full month in the Program.[9] The Exchange notes that both the current and proposed methodology rely on recently incurred Eligible Fixed Costs to predict anticipated Eligible Fixed Costs. For current program Participants the Exchange relies on November costs; whereas, for later-joining Program participants, the Exchange would rely on costs incurred in the Floor Broker's first full month in the Program. The Exchange believes that this approach allows the Exchange the flexibility to offer the FB Prepay Program to Floor Brokers that did not enroll before the end of the prior calendar year, including/especially Floor Brokers new to the Exchange, without putting these Floor Brokers at a competitive disadvantage.

Although the Exchange cannot predict with certainty whether the proposed changes to the FB Prepay Program would encourage Floor Brokers to participate in the program or to increase their manual billable volume, the Exchange believes that the proposed changes would continue to incent Floor Brokers to participate in the FB Prepay Program by adding flexibility to the structure of the Program, including by allowing Floor Brokers to join the Program after the first of the year and increasing the Maximum Combined Rebate/Credit. All Floor Brokers are eligible to participate in the FB Prepay Program and qualify for the proposed rebates.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[11] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12]

There are currently 17 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[13] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in November 2023, the Exchange had less than 12% market share of executed volume of multiply-listed equity and ETF options trades.[14]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, modifications to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The Exchange believes that the proposed changes are reasonable because they are designed to continue to incent Floor Brokers to increase the number of manual transactions sent to the Exchange by offering them rebates on manual transactions with at least one billable side. The Exchange also believes that the proposed higher maximum monthly amount that a firm could earn from Submitting Broker QCC credits and Floor Broker rebates on manual billable volume (*i.e.,* the Maximum Combined Rebate/Credit) is reasonable because it is set at an amount that is designed to encourage Floor Brokers to direct QCC transactions and manual billable volume to the Exchange to receive the existing credits and proposed rebates.

With respect to the FB Prepay Program, the Exchange also believes that the proposed changes are reasonable because participation in the program is optional, and Floor Brokers can elect to participate in the program to be eligible for the rebates offered through the Manual Billable Rebate Program or not. The Exchange also believes that the proposed modification of the FB Prepay Program is reasonable because it is designed to continue to encourage Floor Brokers to participate in the FB Prepay Program, and to provide liquidity on the Exchange. Specifically, the Exchange believes that the proposed continuation of the FB Prepay Program to offer participating Floor Brokers rebates on manual billable volume is reasonable because it would maintain both the incentives offered to Floor Brokers and the qualification basis for such incentives; all Floor Brokers participating in the FB Prepay Program would be eligible for the same rebate on manual billable volume and would qualify for the same additional rebate on manual billable volume by meeting a set volume threshold (which the Exchange believes is reasonable and is attainable based on manual billable volume rebates earned by Floor Brokers).

To the extent that the continued aspects of the program continue to attract more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution, which, in turn, promotes just and

[8] *See* proposed Fee Schedule, FB Prepay Program (providing, in relevant part, that ''[t]o participate in the FB Prepay Program after the first of the year, Floor Broker organizations must notify the Exchange in writing by emailing *optionsbilling@nyse.com,* indicating a commitment to submit prepayment for the balance of the calendar year'' and that the notification ''email to enroll in the Program must originate from an officer of the Floor Broker organization and represents a binding commitment through the balance of the calendar year.'').

[9] *See* proposed Fee Schedule, FB Prepay Program.

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) and (5).

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[13] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[14] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.,* the Exchange's market share in equity-based options decreased from 12.31% for the month of November 2022 to 11.67% for the month of November 2023.

equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system. The Exchange notes that all market participants stand to benefit from any increase in volume entered by Floor Brokers, which could promote market depth, facilitate tighter spreads, and enhance price discovery, to the extent the proposed change encourages Floor Brokers to utilize the Exchange as a primary trading venue, and may lead to a corresponding increase in order flow from other market participants. In addition, any increased liquidity on the Exchange would result in enhanced market quality for all participants.

The Exchange also believes that the proposed change to modify the Program to remove reference to a specific year is reasonable because it would prevent the Exchange from using a benchmark based on a stale date and would add flexibility to the Program (insofar as it would not need to be revised each year). In addition, the proposed change to allow Floor Brokers to join the Program after the first of the year—by prepaying an amount (to cover the balance of the year) based on their Eligible Fixed Costs incurred in their first month in the Program—is reasonable for several reasons. First, the proposed method used to determine the prepayment amount for any later-joining Floor Brokers is analogous to the Exchange's current method of determining the prepayment amount for Program participants (*i.e.,* prepayment amount is based on the Eligible Fixed Costs recently-incurred). Second, the Exchange believes that the proposed method of determining a (later-joining) Floor Broker's prepayment amount would provide the most accurate basis for anticipating that Floor Broker's future Eligible Fixed Costs. Moreover, the Exchange believes that this approach would allow the Exchange the flexibility to offer the FB Prepay Program to later-joining Floor Brokers, including/especially Floor Brokers new to the Exchange, without putting these Floor Brokers at a competitive disadvantage.

To the extent the continuation of the program would continue to attract greater volume and liquidity, the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The Exchange's fees are constrained by intermarket competition, as Floor Brokers may direct their order flow to any of the 17 options exchanges, including an exchange offering Floor Broker rebates on manual transactions.[15] Thus, Floor Brokers have a choice of where they direct their order flow, including their manual transactions. The proposed rule changes are designed to continue to incent Floor Brokers to direct liquidity and, in particular, manual transactions to the Exchange. In addition, to the extent Floor Brokers are incented to continue to aggregate their trading activity at the Exchange, that increased liquidity could promote market depth, price discovery and improvement, and enhanced order execution opportunities for market participants.

Finally, the proposed changes to remove superfluous or obsolete text from the FB Prepay Program, are reasonable because they would add clarity, transparency, and internal consistency to the Fee Schedule to the benefit of all market participants.

The Proposed Rule Change Is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits because the proposal is based on the amount and type of business transacted on the Exchange. Floor Brokers are not obligated to participate in the FB Prepay Program, and those who do can choose to execute manual billable volume to earn rebates through the Manual Billable Rebate Program or not. In addition, the Manual Billable Rebate Program continues to be equally available to all Floor Brokers that participate in the FB Prepay Program and the proposed monthly limit on the amount that firms could earn from Floor Broker manual billable rebates and Submitting Broker QCC credits combined would apply to all firms equally (*i.e.,* the Maximum Combined Rebate/Credit).

The Exchange also notes that the proposed changes are designed to encourage Floor Brokers that have previously enrolled in the FB Prepay Program to reenroll for the upcoming year, as well as to attract Floor Brokers that have not yet participated in the program. Moreover, the Exchange believes that the proposed modifications to the FB Prepay Program are an equitable allocation of fees and credits because they would apply to participating Floor Brokers equally and are intended to encourage the role performed by Floor Brokers in facilitating the execution of orders via open outcry, a function which the Exchange wishes to support for the benefit of all market participants.

The Exchange also believes that the proposed change to modify the Program to remove reference to a specific year is equitable because it would prevent the Exchange from using a benchmark based on a stale date. In addition, the proposed change to allow Floor Brokers to join the Program after the first of the year—by prepaying an amount (to cover the balance of the year) based on their Eligible Fixed Costs incurred in their first month in the Program—is equitable for several reasons. First, the proposed method used to determine the prepayment amount for any later-joining Floor Brokers is analogous to the Exchange's current method of determining the prepayment amount for Program participants (*i.e.,* prepayment amount is based on the Eligible Fixed Costs recently-incurred). Second, the Exchange believes that the proposed method of determining a (later-joining) Floor Broker's prepayment amount would provide the most accurate basis for anticipating that Floor Broker's future Eligible Fixed Costs. Moreover, the Exchange believes that this approach would allow the Exchange the flexibility to offer the FB Prepay Program to later-joining Floor Brokers, including/especially Floor Brokers new to the Exchange, without putting these Floor Brokers at a competitive disadvantage.

Moreover, the proposed changes are designed to continue to incent Floor Brokers to encourage OTP Holders to aggregate their executions at the Exchange as a primary execution venue. To the extent that the proposed change achieves its purpose in attracting more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes the proposed change is not unfairly discriminatory because it is based on the amount and type of business transacted on the Exchange. Floor Brokers are not obligated to execute manual billable transactions or participate in the FB

[15] *See id.*

Prepay Program, and the proposed rebates offered through the Manual Billable Rebate Program are available to all Floor Brokers that participate in the FB Prepay Program on a non-discriminatory basis. The proposed changes are designed to add flexibility to the FB Prepay Program by offering all participating Floor Brokers the same increased Maximum Combined Rebate/Credit and to encourage Floor Brokers to utilize the Exchange as a primary trading venue for all transactions (if they have not done so previously) and increase manual billable volume sent to the Exchange.

The Exchange also believes that the proposed change to modify the Program to remove reference to a specific year is not unfairly discriminatory because it would apply equally to all Program participants and would prevent the Exchange from using a benchmark based on a stale date. In addition, the proposed change to allow Floor Brokers to join the Program after the first of the year—by prepaying an amount (to cover the balance of the year) based on their Eligible Fixed Costs incurred in their first month in the Program—is not unfairly discriminatory for several reasons. First, the proposed method used to determine the prepayment amount for any later-joining Floor Brokers is analogous to the Exchange's current method of determining the prepayment amount for Program participants (*i.e.,* prepayment amount is based on the Eligible Fixed Costs recently-incurred). Second, the Exchange believes that the proposed method of determining a (later-joining) Floor Broker's prepayment amount would provide the most accurate basis for anticipating that Floor Broker's future Eligible Fixed Costs. Moreover, the Exchange believes that this approach would allow the Exchange the flexibility to offer the FB Prepay Program to later-joining Floor Brokers, including/especially Floor Brokers new to the Exchange, without putting these Floor Brokers at a competitive disadvantage.

To the extent that the proposed continuation of (and modifications to) the Program attracts more manual transactions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [16]

Intramarket Competition. The continuation of the rebates on manual billable volume is designed to attract additional order flow to the Exchange (particularly in manual billable transactions), which could increase the volumes of contracts traded on the Exchange. The proposed modification of the FB Prepay Program is likewise intended to incent Floor Brokers specifically to direct manual billable transactions to the Exchange, as well as encourage Floor Brokers to participate in the Program. The continued rebates would be available to all similarly situated Floor Brokers that participate in the FB Prepay Program. Greater liquidity benefits all market participants on the Exchange, and increased manual transactions could increase opportunities for execution of other trading interest. The proposed Maximum Combined Rebate/Credit would likewise apply equally to all similarly situated Floor Brokers.

To the extent that the proposed continuation of the program imposes an additional competitive burden on non-Floor Brokers, the Exchange believes that any such burden would be appropriate because all market participants stand to benefit from any increase in volume entered by Floor Brokers because an increase in trading volume could promote market depth, facilitate tighter spreads, and enhance price discovery. In addition, any increased liquidity on the Exchange would result in enhanced market quality for all participants.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 17 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[17] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in November 2023, the Exchange had less than 12% market share of executed volume of multiply-listed equity and ETF options trades.[18]

The Exchange believes that the proposed changes reflect this competitive environment because they modify the Exchange's fees and rebates in a manner designed to continue to incent OTP Holders to direct trading interest (particularly manual transactions) to the Exchange, to provide liquidity and to attract order flow. To the extent that Floor Brokers are encouraged to participate in the FB Prepay Program and/or incented to utilize the Exchange as a primary trading venue for all transactions, all of the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

The Exchange further believes that the proposed change could promote

[16] *See* Reg NMS Adopting Release, *supra* note 12, at 37499.

[17] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[18] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.,* the Exchange's market share in equity-based options decreased from 12.31% for the month of November 2022 to 11.67% for the month of November 2023.

competition between the Exchange and other execution venues, including those that currently offer rebates on manual transactions by encouraging additional orders to be sent to the Exchange for execution.

Finally, the proposed changes to remove superfluous or obsolete text from the FB Prepay Program are not designed to address any competitive issue but are instead designed to add clarity, transparency, and internal consistency to the Fee Schedule.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [19] of the Act and subparagraph (f)(2) of Rule 19b–4 [20] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [21] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEARCA–2024–10 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSEARCA–2024–10. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEARCA–2024–10 and should be submitted on or before February 23, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–02068 Filed 2–1–24; 8:45 am]

BILLING CODE 8011–01–P

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(2).

[21] 15 U.S.C. 78s(b)(2)(B).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 35118; 812–15403]

Investment Managers Series Trust and Liberty Street Advisors, Inc.

January 29, 2024.

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: Investment Managers Series Trust and Liberty Street Advisors, Inc.

FILING DATES: The application was filed on November 2, 2022 and amended on April 25, 2023 and September 5, 2023.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on February 23, 2024, 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: Diane Drake, Esq., *diane.drake@mfac-ca.com,* Investment Managers Series Trust, 235 West Galena Street, Milwaukee, WI 53212, and Laurie Anne Dee, Esq., *laurie.dee@morganlewis.com,* Morgan, Lewis & Bockius LLP, 600 Anton Boulevard, Suite 1800, Costa Mesa, CA 92626–7653.

FOR FURTHER INFORMATION CONTACT: Christopher D. Carlson, Senior Counsel, or Daniele Marchesani, Assistant Chief

Counsel, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' second amended application, dated September 5, 2023, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field on the SEC's EDGAR system.

The SEC's EDGAR system may be searched at *https://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–02060 Filed 2–1–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 89 FR 5949, January 29, 2024.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, January 31, 2024, at 9:30 a.m.

CHANGES IN THE MEETING: The Open Meeting scheduled for Wednesday, January 31, 2024, at 9:30 a.m., to be held in the Auditorium LL–002 at the Commission's headquarters, 100 F Street NE, Washington, DC 20549 and simultaneously webcast on the Commission's website at *www.sec.gov,* has been postponed to Tuesday, February 6, 2024, at 10:00 a.m.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: January 30, 2024.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–02165 Filed 1–31–24; 11:15 am]

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DEPARTMENT OF STATE

[Public Notice: 12315]

Notice of Determinations; Culturally Significant Objects Being Imported for Conservation and Exhibition—Determinations: ''Guillaume Lethière'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to an agreement with their foreign owner or custodian for temporary display in the exhibition ''Guillaume Lethière'' at the Sterling and Francine Clark Art Institute, Williamstown, Massachusetts, and at possible additional exhibitions or venues yet to be determined, and for temporary conservation at the Williamstown + Atlanta Art Conservation Center, Williamstown, Massachusetts, and at possible additional venues yet to be determined, are of cultural significance, and, further, that their temporary conservation and exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024–02080 Filed 2–1–24; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 12316]

30-Day Notice of Proposed Information Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to March 4, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Brandi Beam, who may be reached on 202–996–1881 or at *informationcollections@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.
- *OMB Control Number:* 1405–0193.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Office of Directives Management, A/GIS/DIR.
- *Form Number:* Various public surveys.
- *Respondents:* Individuals responding to Department of State customer service evaluation requests.
- *Estimated Number of Respondents:* 2,000,000.
- *Estimated Number of Responses:* 2,000,000.
- *Average Time per Response:* 3.5 minutes.
- *Total Estimated Burden Time:* 116,667 annual hours.
- *Frequency:* Once per request.

• *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The information collection activity will garner qualitative customer feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. This qualitative feedback will provide insights into customer perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Methodology

Respondents will fill out a brief customer survey after completing their interaction with a Department Program Office or Embassy. Surveys are designed to gather feedback on the customer's experiences.

Zachary A. Parker,

Director, Office of Directives Management, Department of State.

[FR Doc. 2024–02132 Filed 2–1–24; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2024–0189]

Agency Information Collection Activities: Requests for Comments; Clearance of a New Approval of Information Collection: Unmanned Aircraft System (UAS) Integration at Airports and Necessary Planning, Design, and Physical Infrastructure Needs

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 for a new information collection. The collection involves conducting research in the form of interviews with aviation stakeholders (*e.g.,* airport/droneport operators, private entities, original equipment manufacturers, unmanned aircraft system (UAS) industry vendors, academia, representatives of the military, aviation stakeholders, etc.) to catalog current and planned droneport planning, design, and infrastructure needs, as well as find out which airports are integrating UAS into the airport environment. During each interview, the FAA will ask the stakeholders a specific set of questions, and if necessary, fact-specific follow-up questions will be posed to clarify and enhance the respondent's answers to the specified set of questions. The information to be collected is necessary because it will allow the FAA to understand how aviation stakeholders are integrating UAS into existing airport design standards/infrastructure and standalone facilities also referred to as droneports. Currently, no formal FAA definition of droneport currently exists. Based on the results of this research effort, the FAA may develop a formal definition for a droneport. For the purposes of this research effort, a modified version of the 14 Code of Federal Regulations Part 1 definition of 'airport' is used to define droneport: 'an area of land or water that is used or intended to be used for the landing and takeoff of UAS aircraft, and includes its buildings and facilities, if any.' The information collected will also be used to help the FAA to shape future droneport research efforts and possible standards and guidance material.

DATES: Written comments should be submitted by April 2, 2024.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By Mail: Michael DiPilato, Airport Research Specialist, FAA Airport Technology Research and Development Branch (ANG–E26), FAA William J. Hughes Technical Center, Bldg. 301 (FAA Hangar), Atlantic City, NJ 08405.

By Fax: 609–485–4845.

FOR FURTHER INFORMATION CONTACT: Michael DiPilato by email at: *michael.dipilato@faa.gov;* phone: 609–485–7249.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–XXXX.

Title: Unmanned Aircraft System (UAS) Integration at Airports and Necessary Planning, Design, and Physical Infrastructure Needs.

Form Numbers: None.

Type of Review: New information collection.

Background: The aviation industry is experiencing expedited growth in new and innovative aircraft design and operation. One of these concepts has been unmanned aircraft systems (UAS), commonly referred to as 'drones'. The proliferation of interest in and use of

UAS has led to significant policy and regulatory adaptations to safely integrate these platforms into the airport environment. The FAA defines a UAS as 'an unmanned aircraft and the equipment necessary for the safe and efficient operation of that aircraft. An unmanned aircraft is a component of a UAS. It is defined by statute as an aircraft that is operated without the possibility of direct human intervention from within or on the aircraft (Pub. L. 112–95, Section 331(8)).' As the technology and its use continues to mature, the FAA is committed to conducting research and providing policy and guidance to ensure the safe operation of UAS, whether autonomous or remotely piloted, in and around the airport environment. As more UAS Concept of Operations (CONOPS) propose operations involving the airport environment and droneports, there is a need to consider if unique requirements or recommendations for the planning, design, and physical infrastructure needs are necessary.

On May 9, 2023, the FAA's Office of Airports—Airport Emerging Entrants Division (AAS–200) officially sent the FAA's Airport Technology Research and Development Branch (ATR) a '*Request for Research*' to conduct research on Unmanned Aircraft System (UAS) Integration at Airports and Necessary Planning, Design, and Physical Infrastructure Needs. This '*Request for Research*' was reviewed and approved by the Research, Engineering, and Development Advisory Committee (REDAC) Subcommittee on Airports. Established in 1989, the FAA's REDAC provides advice and recommendations to the FAA Administrator on the needs, objectives, plans, approaches, content, and accomplishments of the aviation research portfolio. The REDAC also assists in ensuring FAA present and future aviation research activities are coordinated with similar research being conducted outside the FAA. The REDAC Subcommittee on Airports includes members from the following affiliations: academia, aircraft manufacturers, an airline pilot union, airport authorities, aviation industry organizations, and environmental advocates.

As part of the Request for Research (*i.e.,* research effort), discussed above, the FAA will conduct interviews with stakeholders, in the form of in-person and virtual meetings, with representatives from the following organizations: airports, droneports, private entities, original equipment manufacturers, UAS industry vendors, the military, international aviation community, and academia. During each interview, the FAA will ask the stakeholders a specific set of questions, and if necessary, fact-specific follow-up questions will be posed to clarify and enhance the respondent's answers to the specified set of questions.

The purpose of these interviews will be to catalog and inventory current and prospective droneports and gather key insights from these operators. In addition, the research team will document stakeholder's experiences/lessons learned with integrating or operating UAS at airports and independent droneport operations.

The results from this research effort will be summarized in a final report and will be used to shape the FAA's operational evaluations and possible development of standards and guidance documents pertaining to planning, design, and physical infrastructure needs, as well as safety standards, for fixed-wing and rotary operations. This effort will primarily focus on UAS aircraft weighing 55 pounds or more and include operational considerations for cargo transport. Vehicles with weights lower than 55 pounds will be considered where applicable. Both fixed wing and rotary operational will be considered to create a baseline understanding before establishing infrastructure design requirements and safety standards for existing and standalone facilities referred to as a droneport.

Respondents: Approximately 100 airport operators, droneport operators, original equipment manufacturers, private entities, UA industry vendors, representatives of the military, the international aviation community, and academia.

Frequency: Information will be collected one to two times annually.

Estimated Average Burden per Response: 2.5–4.5 hours.

Estimated Total Annual Burden: 250–400 hours.

Issued in Atlantic City, NJ, on January 29, 2024.

Michael DiPilato,

Airport Research Specialist, FAA Aviation Research Division, Airport Technology Research and Development Branch (ANG–E26).

[FR Doc. 2024–02054 Filed 2–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Aviation Rulemaking Advisory Committee (ARAC) meeting.

SUMMARY: This notice announces a meeting of the ARAC.

DATES: The FAA will hold the meeting on Thursday, March 21, 2024, from 1 p.m. to 4 p.m. eastern time.

The FAA must receive requests to attend the meeting by Monday, March 11, 2024.

The FAA must receive requests for accommodations to a disability by Monday, March 11, 2024.

The FAA must receive any written materials to during the meeting by Monday, March 11, 2024.

ADDRESSES: The meeting will be held at the Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, and virtually on Zoom. However, if the FAA is unable to hold the meeting in person due to circumstances outside of its control, the FAA will hold a virtual meeting and notify registrants with the meeting details and post any updates on the FAA Committee website. Members of the public who wish to observe the meeting must RSVP by emailing *9-awa-arac@faa.gov.* General committee information, including copies of the meeting minutes, will be available on the FAA Committee website at *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/.*

FOR FURTHER INFORMATION CONTACT: Aliah Duckett, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267–7489; email *9-awa-arac@faa.gov.* Any committee-related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

The ARAC was created under the Federal Advisory Committee Act (FACA), in accordance with title 5 of the United States Code (5 U.S.C. 1001) to provide advice and recommendations to the FAA concerning rulemaking activities, such as aircraft operations, airman and air agency certification, airworthiness standards and certification, airports, maintenance, noise, and training.

II. Agenda

At the meeting, the agenda will cover the following topics:

- Status Updates
  - Active Working Groups
  - Transport Airplane and Engine (TAE) Subcommittee
- Recommendation Reports
- Any Other Business

Detailed agenda information will be posted on the FAA Committee website address listed in the **ADDRESSES** section at least one week in advance of the meeting.

III. Public Participation

The meeting will be open to the public for virtual or in person attendance on a first-come, first-served basis, as there is limited space. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section and provide the following information: full legal name, country of citizenship, and name of your industry association or applicable affiliation. Please indicate if you plan to observe the meeting in person or virtually. The FAA will email registrants the meeting access information in a timely manner prior to the start of the meeting.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

The FAA is not accepting oral presentations at this meeting due to time constraints. Any member of the public may present a written statement to the committee at any time. The public may present written statements to ARAC by providing a copy to the Designated Federal Officer via the email listed in the **FOR FURTHER INFORMATION CONTACT** section.

Issued in Washington, DC, on January 29, 2024.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2024–02091 Filed 2–1–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0141]

Parts and Accessories Necessary for Safe Operation; Exemption Renewal for Stoneridge, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of provisional renewal of exemption; request for comments.

SUMMARY: FMCSA announces its decision to provisionally renew Stoneridge, Inc.'s (Stoneridge) exemption, which will allow motor carriers to operate commercial motor vehicles (CMV) with the company's MirrorEye™ Camera Monitor System (CMS) installed as an alternative to the two rear-vision mirrors required by the Federal Motor Carrier Safety Regulations (FMCSRs). The exemption is renewed for 5 years, unless revoked earlier.

DATES: This renewed exemption is effective February 13, 2024, through February 12, 2029, unless revoked earlier. Comments must be received on or before March 4, 2024.

ADDRESSES: You may submit comments identified by docket number FMCSA–2018–0141 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/docket/FMCSA-2018-0141/document.* Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

FOR FURTHER INFORMATION CONTACT: Mr. David Sutula, Chief, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–9209; *MCPSV@dot.gov.* If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2018–0141), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *https://www.regulations.gov/docket/FMCSA-2018-0141/document,* click on this notice, click ''Comment,'' and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at *brian.g.dahlin@dot.gov.* At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

B. Viewing Comments and Documents

To view any documents mentioned as being available in the docket, go to *https://www.regulations.gov/docket/FMCSA-2018-0141/document* and choose the document to review. To view

comments, click this notice, then click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice DOT/ALL 14 (Federal Docket Management System (FDMS)), which can be reviewed under the ''Department Wide System of Records Notices'' at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices.* The comments are posted without edit and are searchable by the name of the submitter.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b)(2) and 49 CFR 381.300(b) to renew an exemption from the FMCSRs for subsequent 5-year periods if it finds that such exemption would likely maintain a level of safety that is equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). Stoneridge has requested a 5-year extension of its current exemption.

III. Background

Current Regulatory Requirements

FMCSA requires in 49 CFR 393.80(a) that each bus, truck, and truck tractor be equipped with two rear-vision mirrors, one at each side. The mirrors must be positioned to reflect to the driver a view of the highway to the rear and the area along both sides of the CMV. Section 393.80(a) also requires that the National Highway Traffic Safety Administration's standard for mirrors on motor vehicles in Federal Motor Vehicle Safety Standard (FMVSS) No. 111 be met. Paragraph S7.1 of FMVSS No. 111 provides requirements for mirrors on multipurpose passenger vehicles and trucks with a gross vehicle weight rating (GVWR) greater than 4,536 kg and less than 11,340 kg and each bus, other than a school bus, with a GVWR of more than 4,536 kg. Paragraph S8.1 provides requirements for mirrors on multipurpose passenger vehicles and trucks with a GVWR of 11,340 kg or more.

Original Exemption

In its original exemption application, Stoneridge noted that the MirrorEye™ CMS consists of multiple digital cameras mounted on the exterior of the CMV and enclosed in an aerodynamic package that provides both environmental protection for the cameras and a mounting location for optimal visibility. Each camera has video processing software that presents a clear, high-definition image to the driver by means of a monitor mounted to each A-pillar of the CMV, *i.e.,* the structural member between the windshield and door of the cab. Stoneridge explained that attaching the monitors to the A-pillars avoids the creation of incremental blind spots and eliminates the blind spots associated with conventional mirrors. Stoneridge stated that its MirrorEye™ CMS meets or exceeds the visibility requirements provided in FMVSS No. 111 based on several factors:

- *Greater field of view than conventional mirrors*—Mirrors are replaced by wide angle, narrow angle, and look-down cameras expanding the field of view by an estimated 25 percent.
- *Fail-safe design*—The MirrorEye™ CMS has independent video processing of multiple camera images so that in the unlikely event of an individual camera failure, the other camera images continue to be displayed. This ensures that real-time images are continuously displayed without interruption.
- *Augmented and enhanced vision quality*—The use of high-definition digital cameras provides for color night vision, low light sensitivity, and trailer panning capabilities. This assists with night driving and operating under other low lighting conditions and provides for glare reduction.
- *Trailer panning*—The MirrorEye™ CMS automatically tracks the end of the trailer to keep it in view while the vehicle is moving forward. Stoneridge stated this feature could eliminate collisions associated with the CMV driver making a right-hand turn and the CMV striking a pedestrian or bicyclist during the turn.

Stoneridge noted that the use of its MirrorEye™ CMS may help to reduce driver fatigue by requiring less head movement by drivers compared to the number of head movements needed to use conventional mirrors. Stoneridge noted further that use of its MirrorEye™ CMS provides improved fuel economy because the housing for the system is more aerodynamic than the conventional mirrors required by § 393.80(a).

On February 21, 2019, following notice and consideration of the comments received, FMCSA determined that use of Stoneridge's MirrorEye™ CMS would likely maintain a level of safety that is equivalent to or greater than the level of safety that would be obtained by complying with § 393.80(a) and granted Stoneridge's exemption request for a 5-year period (84 FR 5557). In its decision, FMCSA noted that the use of the MirrorEye™ CMS provides CMV drivers with an enhanced field of view when compared to the required rear-vision mirrors because (1) it eliminates the blind spots on both sides of the vehicle created by the required rear-vision mirrors, (2) the multi-camera system expands the field of view compared to the required rear-vision mirrors by an estimated 25 percent, and (3) the trailer panning feature automatically tracks the end of the trailer to keep it in view in forward motion.

Additionally, FMCSA highlighted that the MirrorEye™ CMS uses high-definition cameras and monitors that include features such as color night vision, low light sensitivity, and light and glare reduction that together provide drivers with improved vision when compared to traditional rear-vision mirrors. FMCSA also noted that the MirrorEye™ CMS includes features such as self-cleaning lenses/cameras to eliminate problems with rain and dirt, a feature that is not required for traditional rear-vision mirrors, and an advanced defrosting system for winter driving. FMCSA did not find reason for concern about the possibility of electronic malfunctions compromising operation of the system or the possibility of increased driver distraction.

Finally, FMCSA noted that the FMCSRs impose several operational controls that will help ensure that the MirrorEye™ CMS is always functioning properly. Section 396.7 prohibits any vehicle from being operated in such a condition as to likely cause an accident or breakdown of the vehicle. Section 392.7(a) requires each CMV driver to satisfy themself that a vehicle is in safe condition before operating the vehicle, which would include ensuring that the rear-vision mirrors (or in this case, the MirrorEye™ CMS) are in good working order. Similarly, § 396.13(a) requires that, before driving a vehicle, a driver must be satisfied that the vehicle is in safe operating condition. If the MirrorEye™ CMS (effectively functioning as the rear-vision mirrors)

fails during operation, the driver must complete a driver vehicle inspection report at the completion of the workday as required by § 396.11 and the motor carrier must ensure that the defect is corrected.

Application for Renewal of Exemption

In its renewal application, Stoneridge reiterated the previous statements in support of its original exemption request. Stoneridge noted that since the 2019 exemption was granted, the MirrorEye™ CMS has been installed on over 1,000 vehicles in North America, logging over an estimated 100 million miles with no reported incidents caused by the system. Stoneridge stated that a leading fleet recently conducted a controlled study comparing accident costs across 24 million miles driven with the MirrorEye™ CMS to 134 million miles driven without the system. The study showed approximately a 65 percent reduction in accident costs in the group using the MirrorEye™ CMS, including in key use cases such as lane change, left/right turning, and backing. Stoneridge also referenced a study by the German Federal Highway Research Institute that compared CMS with conventional exterior mirrors in a variety of conditions and generally concluded that CMS can provide views comparable to—and in some cases better than—conventional mirror systems.[1] Stoneridge reported that in Europe its MirrorEye™ CMS has been installed on over 1,110 buses and over 2,000 systems have been installed by commercial vehicle original equipment manufacturers. A copy of Stoneridge's request to renew the exemption is available in the docket.

IV. Equivalent Level of Safety Analysis

FMCSA is not aware of any evidence showing that the operation of Stoneridge's MirrorEye™ CMS in accordance with the conditions of the original exemption has resulted in any degradation in safety. Moreover, the information provided by Stoneridge in its application supports that Stoneridge's MirrorEye™ CMS maintains the requisite statutory level of safety. Therefore, for the reasons discussed above and in the prior notice granting the original exemption request, FMCSA concludes that provisionally renewing the exemption granted on February 21, 2019, for a subsequent 5 years, on the terms and conditions set forth in this exemption renewal decision, would likely maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

V. Exemption Decision

A. Grant of Exemption

FMCSA provisionally renews the exemption for a subsequent period of 5 years subject to the terms and conditions of this decision and the absence of adverse public comments that would cause the Agency to revoke the exemption. The exemption from the requirements of 49 CFR 393.80 is otherwise effective February 13, 2024, through February 12, 2029, 11:59 p.m. local time, unless revoked.

B. Applicability of Exemption

During the temporary exemption period, motor carriers operating CMVs may install and use the Stoneridge MirrorEye™ CMS in lieu of the two rear-vision mirrors required by § 393.80.

C. Terms and Conditions

1. This exemption is limited to the Stoneridge MirrorEye™ CMS installed on CMVs and does not apply to any other camera-based mirror replacement system/technology.

2. Drivers operating CMVs under this exemption must inspect the MirrorEye™ CMS each time before operating the CMV and be satisfied that it is in proper working order.

3. Drivers operating CMVs under this exemption must inspect the MirrorEye™ CMS at the end of each day and note any defects in the equipment on the driver vehicle inspection report. The motor carrier must repair any defects noted by the driver before it operates the CMV again.

4. The motor carrier must periodically inspect the MirrorEye™ CMS in addition to the existing inspection required at least once every 12 months.

D. 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 that conflicts with or is inconsistent with this exemption with respect to a person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

E. Revocation

The exemption will be valid for 5 years as provided in section V.A. above, unless revoked earlier by FMCSA. FMCSA does not believe that motor carriers, drivers, and CMVs covered by the exemption will experience any deterioration of their safety record. However, should this occur, FMCSA will take all steps necessary to protect the public interest, including revocation of the exemption without prior notice. The exemption will be immediately revoked if: (1) motor carriers, drivers, and/or CMVs fail 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 49 U.S.C. 31136 or chapter 313.

Interested parties possessing information that would demonstrate that this exemption or motor carriers operating CMVs utilizing the MirrorEye™ CMS installed as an alternative to two rear-vision mirrors are not achieving the requisite statutory level of safety should immediately notify FMCSA by email at *MCPSV@DOT.GOV*. The Agency will evaluate any such information and, if safety is being compromised or if the continuation of the exemption is not consistent with the goals and objectives of 49 U.S.C. 31136 or chapter 313, will take immediate steps to revoke the exemption.

VI. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on Stoneridge's application for renewal of its exemption from § 393.80. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Sue Lawless,

Acting Deputy Administrator.

[FR Doc. 2024–02081 Filed 2–1–24; 8:45 am]

BILLING CODE 4910–EX–P

[1] Schmidt, E.A., et al. ''Camera-Monitor Systems as a Replacement for Exterior Mirrors in Cars and Trucks.'' Federal Highway Research Institute (Germany), 2015.

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley Smith, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Enforcement, Compliance & Analysis, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*ofac.treasury.gov*).

Notice of OFAC Action(s)

On January 30, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. AL-SAYYID, Sarah Jamal Muhammad (Arabic: سارة جمال محمد السيد) (a.k.a. GAMAL, Sarah; a.k.a. JAMAL, Sarah), Egypt; DOB 07 Jul 1985; POB Egypt; nationality Egypt; Gender Female; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

   Designated pursuant to section 1(a)(iii)(C) of Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism," 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, "Modernizing Sanctions To Combat Terrorism," 84 FR 48041 (E.O. 13224, as amended), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ISLAMIC STATE OF IRAQ AND THE LEVANT, a person whose property and interests in property are blocked pursuant to E.O. 13224.

2. SALIM, Mu'min al-Mawji Mahmud (Arabic: مؤمن الموجي محمود سليم) (a.k.a. AL-MUJAHEDEEN, Taqni; a.k.a. AL-MUJAHIDIN, Taqni; a.k.a. SALIM, Mu'min al-Mawgy Mahmud; a.k.a. SALIM, Mu'min al-Mogy Mahmud), Egypt; DOB 16 Oct 1991; POB Egypt; nationality Egypt; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

   Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ISLAMIC STATE OF IRAQ AND THE LEVANT, a person whose property and interests in property are blocked pursuant to E.O. 13224.

3. GUZEL, Faruk (Latin: GÜZEL, Faruk), Malatya, Turkey; DOB 01 Oct 1968; POB Malatya, Turkey; nationality Turkey; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 54163439634 (Turkey) (individual) [SDGT] (Linked To: ISLAMIC STATE OF IRAQ AND THE LEVANT).

   Designated pursuant to section 1(a)(iii)(C) of E.O. 13224, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, ISLAMIC STATE OF IRAQ AND THE LEVANT, a person whose property and interests in property are blocked pursuant to E.O. 13224.

Dated: January 30, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–02104 Filed 2–1–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley T. Smith, Director, tel.: 202–622–6922; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

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 Action

On January 23, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. PEARSON, Adam Richard (a.k.a. ANSING, Michael; a.k.a. DAVIS, Mason), British Columbia, Canada; DOB 14 May 1994; alt. DOB 28 Apr 1995; POB Canada; nationality Canada; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport QG963705 (Canada) (individual) [IRAN-HR] (Linked To: RYAN, Damion Patrick John).

   Designated pursuant to 1(a)(ii)(B) of Executive Order 13553 of September 28, 2010, "Blocking Property of Certain Persons With Respect to Serious Human Rights Abuses by the Government of Iran and Taking Certain Other Actions" (E.O. 13553), 75 FR 60567, October 1, 2010, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, DAMION PATRICK JOHN RYAN, a person whose property and interests in property are blocked pursuant to E.O. 13553.

2. RYAN, Damion Patrick John (a.k.a. JOHN, Damion Patrick; a.k.a. RYAN, Damion Patrick; a.k.a. "HENRY, John"; a.k.a. "JOHN, Damien"; a.k.a. "JOHN, Damion"; a.k.a. "PATRICK, Damion"; a.k.a. "RYAN, Damien"; a.k.a. "RYAN, John"), British Columbia, Canada; DOB 14 Oct 1980; POB Canada; nationality Canada; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport WQ097521 (Canada); alt. Passport HK184430 (Canada) expires 15 Sep 2026; alt. Passport AK406531 (Canada) expires 11 Jan 2029 (individual) [IRAN-HR] (Linked To: ASAN, Nihat Abdul Kadir).

   Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, NIHAT ABDULKADIR ASAN, a person whose property and interests in property are blocked pursuant to E.O. 13553.

3. OZTUNC, Ekrem Abdulkerym (a.k.a. OZTUNC, Ekrem), Orumiyeh, West Azerbaijan, Iran; DOB 07 Oct 1984; POB Yuksekova, Turkey; nationality Turkey; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport U01292672 (Turkey) expires 01 Feb 2021 (individual) [IRAN-HR] (Linked To: SHARIFI-ZINDASHTI, Naji Ibrahim).

   Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material or technological support for, or goods or services to or in support of, NAJI IBRAHIM SHARIFI-ZINDASHTI, a person whose property and interests in property are blocked pursuant to E.O. 13553.

4. TAMARZADEH ZAVIEH JAKKI, Shahram Ali Reza (Arabic: شهرام علی رضا تمرزاده زاویه جکی) (a.k.a. TAMARZADEH, Farhad Ali), Orumiyeh, West Azerbaijan, Iran; DOB 31 May 1972; nationality Iran; Additional Sanctions Information -

Subject to Secondary Sanctions; Gender Male; Passport T36369585 (Iran) expires 01 Jan 2021; National ID No. 2850540498 (Iran) (individual) [IRAN-HR] (Linked To: IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY).

Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY, a person whose property and interests in property are blocked pursuant to E.O. 13553.

5. ESFANJANI, Ali (Arabic: علی اسفنجانی), Iran; DOB 15 Aug 1985; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport P30251288 (Iran) expires 01 Jun 2019 (individual) [IRAN-HR] (Linked To: IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY).

   Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY, a person whose property and interests in property are blocked pursuant to E.O. 13553.

6. KOCAK, Ali (Arabic: علی کوچک) (a.k.a. KOCHAK, Ali), Orumiyeh, West Azerbaijan Province, Iran; Turkey; DOB 30 Sep 1985; POB Adiyaman Kahta, Turkey; nationality Turkey; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 20926131442 (Turkey) (individual) [IRAN-HR] (Linked To: SHARIFI-ZINDASHTI, Naji Ibrahim).

   Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, NAJI IBRAHIM SHARIFI-ZINDASHTI, a person whose property and interests in property are blocked pursuant to E.O. 13553.

7. KOCAK, Abdulvahap (Arabic: عبدالوهاب کوچاک) (a.k.a. KOCAK, Abdul Wahab; a.k.a. KOCAK, Abdulvahhab; a.k.a. KOCHAK, Abdulvahap), Turkey; DOB 09 Sep 1999; POB Adiyaman, Turkey; nationality Turkey; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport Ul2429867 (Turkey) expires 18 Mar 2021 (individual) [IRAN-HR] (Linked To: SHARIFI-ZINDASHTI, Naji Ibrahim).

   Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, NAJI IBRAHIM SHARIFI-ZINDASHTI, a person whose property and interests in property are blocked pursuant to E.O. 13553.

8. NASERZADEH, Muhammad Reza (Arabic: محمد رضا ناصرزاده) (a.k.a. NASER ZADEH, Mohammad Reza; a.k.a. NASERZADEH, Mohammadreza; a.k.a. NASIRZADE, Muhammed Reza; a.k.a. NASSER ZADEH, Mohammad Reza), Iran; DOB 01 Jan 1978; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male (individual) [IRAN-HR] (Linked To: IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY).

Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY, a person whose property and interests in property are blocked pursuant to E.O. 13553.

9. ASAN, Nihat Abdul Kadir (Arabic: نيهات عبدالقدير آسان) (a.k.a. ASAN, Nihat; a.k.a. ASAN, Nihat Abdulkadir; a.k.a. ASHAN, Nihat; a.k.a. EBRAHIMIHARKIAN, Ramin; a.k.a. KURD, Ibrahim; a.k.a. "BAHTIYAR"), Orumiyeh, West Azerbaijan, Iran; DOB 01 Oct 1981; alt. DOB 11 Nov 1981; POB Van, Turkey; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport U13927927 (Turkey) expires 25 Jan 2027; National ID No. 2751062326 (Iran) (individual) [IRAN-HR] (Linked To: IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY).

   Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY, a person whose property and interests in property are blocked pursuant to E.O. 13553.

10. HAMIDIRAVARI, Reza (Arabic: رضا□میدی راوری) (a.k.a. RAVARI, Reza), Iran; DOB 31 Oct 1963; nationality Iran; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; Passport V40150378 (Iran) expires 02 Jan 2022 (individual) [IRAN-HR] (Linked To: IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY).

    Designated pursuant to 1(a)(ii)(C) of E.O. 13553 for having acted or purported to act for or on behalf of, directly or indirectly, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY, a person whose property and interests in property are blocked pursuant to E.O. 13553.

11. SHARIFI-ZINDASHTI, Naji Ibrahim (Arabic: ناجی ابراهیم شریفی زیندشتی) (a.k.a. KENANI, Emirhan; a.k.a. SERIFI ZINDASTI, Naci; a.k.a. SERIFI-ZINDASTI, Naci; a.k.a. SHARIFI ZINDASHTI, Naji; a.k.a. SHARIFI-ZINDASHTI, Naji), Orumiyeh, West Azerbaijan, Iran; DOB 31 May 1974; POB Orumiyeh, Iran; nationality Iran; alt. nationality Turkey; Additional Sanctions Information - Subject to Secondary Sanctions; Gender Male; National ID No. 2753229112 (Iran) (individual) [IRAN-HR] (Linked To: IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY).

    Designated pursuant to 1(a)(ii)(B) of E.O. 13553 for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the IRANIAN MINISTRY OF INTELLIGENCE AND SECURITY, a person whose property and interests in property are blocked pursuant to E.O. 13553.

Dated: January 23, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–02052 Filed 2–1–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley Smith, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Enforcement, Compliance & Analysis, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*ofac.treasury.gov*).

Notice of OFAC Action(s)

On January 29, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person is blocked under the relevant sanctions authority listed below.

Individual

1. AL-MOUSSAWI, Hamad (a.k.a. AL MOSAWI, Hamad Yasir Mohsin; a.k.a. AL MUSAWI, Hamad Yasir Mohsin; a.k.a. AL MUSAWI, Hammed Muhsen; a.k.a. AL-MUSAWI, Hamad Yasir Muhsin), Baghdad, Iraq; DOB 12 May 1970; POB Baghdad, Iraq; nationality Iraq; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Passport Al3624852 (Iraq) expires 26 Jun 2026; alt. Passport All035307 (Iraq) expires 01 Apr 2024; National ID No. 00385065 (Iraq) (individual) [SDGT] [IFSR] (Linked To: ISLAMIC REVOLUTIONARY GUARD CORPS (IRGC)—QODS FORCE).

Designated pursuant to section 1(a)(iii)(C) of Executive Order 13224 of September 23, 2001, ''Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism,'' 66 FR 49079, as amended by Executive Order 13886 of September 9, 2019, ''Modernizing Sanctions To Combat Terrorism,'' 84 FR 48041, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the ISLAMIC REVOLUTIONARY GUARD CORPS—QODS FORCE, a person whose property and interests in property are blocked pursuant to Executive Order 13224.

Dated: January 29, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–02053 Filed 2–1–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

United States Mint

Notification of Citizens Coinage Advisory Committee Public Meeting—February 27, 2024

ACTION: Notice of meeting.

Pursuant to United States Code, title 31, section 5135(b)(8)(C), the United States Mint announces the Citizens Coinage Advisory Committee (CCAC) public meeting scheduled for February 27, 2024.

Date: February 27, 2024.

Time: 12 p.m. to 4 p.m. (EST).

Location: Remote via videoconference.

Subject: Review and discussion of reverse candidate designs for the 2025 American Innovation $1 Coins honoring innovations in Florida and Texas; review and discussion of design options for one-cent and five-cent 2026 Semiquincentennial coins; discussion of future themes for the platinum proof program; and potentially additional matters. In addition, a newly appointed member will be sworn in.

Interested members of the public may watch the meeting live stream on the United States Mint's YouTube Channel at *https://www.youtube.com/user/usmint.* To watch the meeting live, members of the public may click on the ''February 27 meeting'' icon under the Live Tab. *Members of the public should call the CCAC HOTLINE at (202) 354–7502 for the latest updates on meeting time and access information.*

The CCAC advises the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals; advises the Secretary of the Treasury with regard to the events, persons, or places to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made; and makes recommendations with respect to the mintage level for any commemorative coin recommended. For members of the public interested in watching on-line, this is a reminder that the remote access is for observation purposes only. Members of the public may submit matters for the CCAC's consideration by email to *info@ccac.gov.*

For Accommodation Request: If you require an accommodation to watch the CCAC meeting, please contact the Office of Equal Employment Opportunity by February 20, 2024. You may submit an email request to *Reasonable.Accommodations@usmint.treas.gov* or call 202–354–7260 or 1–888–646–8369 (TTY).

FOR FURTHER INFORMATION CONTACT: Jennifer Warren, United States Mint Liaison to the CCAC; 801 9th Street NW; Washington, DC 20220; or call 202–354–7208.

(Authority: 31 U.S.C. 5135(b)(8)(C))

Eric Anderson,

Executive Secretary, United States Mint.

[FR Doc. 2024–02121 Filed 2–1–24; 8:45 am]

BILLING CODE 4810–37–P

DEPARTMENT OF VETERANS AFFAIRS

Homeless Providers Grant and Per Diem (GPD) Program Special Need Grant

AGENCY: Department of Veterans Affairs.

ACTION: Notice of Funding Opportunity (NOFO).

SUMMARY: The Department of Veterans Affairs (VA) announces the opportunity of funds in the amount of approximately $5 million per year for up to 2 years under the Grant and Per Diem (GPD)

special need grant program. The special need grants enable the GPD program within VA's Homeless Programs Office to offer financial assistance through a 2-year renewal grant to the 16 currently operational GPD special need grantees to defray the cost of facilitating transitional housing and supportive services for eligible Veterans. Funding offered under this Notice of Funding Opportunity (NOFO) responds to the need to reach Veterans who are homeless or at risk of becoming homeless and who are in one of the special need populations (*i.e.,* chronically mentally ill, frail elderly, individuals who care for minor dependents, terminally ill, or women). This renewal funding will provide assistance to offset operational costs including costs that would not otherwise be incurred, but for the fact that the recipient is providing supportive housing beds in private rooms with private bathrooms for a homeless Veteran population with special needs. This Notice contains information concerning the GPD program, the application process, and amount of funding available. Awards made for program services grants will fund operations beginning on or around October 1, 2024.

DATES: Applications for grants must be received by 4:00 p.m. Eastern Time on April 15, 2024. In the interest of fairness to all competing applicants, this deadline is firm as to date and hour. VA will treat as ineligible for consideration any application that is received after the deadline. Applicants should take this practice into account and submit their materials early to avoid risk of loss of eligibility, unanticipated delays, computer service outages, or other submission-related problems.

ADDRESSES: Copies of the application materials can be downloaded from the program website at *https://www.va.gov/homeless/gpd.asp.* Questions should be referred to *GPDGrants@va.gov.* For detailed program information and requirements, see 38 CFR part 61.

FOR FURTHER INFORMATION CONTACT: Ms. Chelsea Watson, Director VA Homeless Providers GPD Program Office, 813–816–7155 extension 100109 (this is not a toll-free telephone number), or *GPDGrants@va.gov.*

Application Submission: Applicants must submit applications electronically following instructions found at *https://www.va.gov/homeless/gpd.asp.* Applications may not be emailed, mailed, or sent by facsimile (fax). Applications must be received by the Program Office no later than 4:00 p.m. Eastern Time on the application deadline date. Applications must arrive as a complete package.

Materials arriving separately will not be included in the application package for consideration and may result in the application being rejected or not funded.

In the event of certain errors, such as duplicate applications or multiple applications per Employer Identification Number, per VA medical facility catchment area, VA reserves the right to select which application to consider based on the submission dates and times or based on other factors.

Applicants are advised to refer to this NOFO when completing the online application. NOFO content provides supplementary guidance for completing the online application.

Technical Assistance: Information on obtaining technical assistance for preparing a grant application is available on the program website at *https://www.va.gov/homeless/gpd.asp.*

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: GPD Special Need Grant.

Announcement Type: Renewal.

Funding Opportunity Number: VA–GPD–SN–FY2025.

Assistance Instrument: Grant.

Assistance Listing: 64.024, VA Homeless Providers Grant and Per Diem Program.

I. Funding Opportunity Description

Program Purpose and Background

Purpose: Ending and preventing homelessness among Veterans is a priority for VA. VA's Homeless Programs Office constitutes the Nation's largest integrated network of homelessness, housing, prevention, and rehabilitation services for Veterans. These programs are designed to help Veterans live as self-sufficiently and independently as possible. The foundation for these programs is based on Housing First principles combined with supportive services to ensure Veterans are able to end the cycle of homelessness.

Since 1994, the GPD program has provided Veterans who are experiencing homelessness with community-based transitional housing, supportive services such as case management, and more. These services assist Veterans in attaining or retaining permanent residence. Several types of grants are offered under the umbrella of the GPD program. The grants are designed to meet Veterans at various stages as they move to housing stability. The community organizations who receive the grants offer focused housing stability support through a variety of service models. The GPD program plays a vital role in the continuum of homeless services.

Background: Ending Veteran homelessness requires multifaceted approaches. This NOFO represents one such approach. This NOFO responds to the need in communities to reach Veterans who are homeless or at risk of becoming homeless and who are in one of the special need populations (i.e., chronically mentally ill, frail elderly, individuals who care for minor dependents, terminally ill, or women). The renewal funding will provide assistance to offset operational costs including costs that would not otherwise be incurred, but for the fact that the recipient is providing supportive housing beds in private rooms with private bathrooms for a homeless Veteran population with special needs. Grants funded from this NOFO will increase housing stability for Veterans. VA is committed to supporting community-based organizations as they transform projects to meet the challenge of ending homelessness among Veterans.

Program Description

Goals and Objective: The goals of projects under assistance listing 64.024, VA Homeless Providers Grant and Per Diem program, are to provide transitional housing and supportive services to Veterans experiencing homelessness as they move toward and retain permanent housing. To achieve these goals, the objective of this NOFO is to provide renewal funding for per diem payments to defray the cost of facilitating housing stabilization within private rooms with private bathrooms for special need populations of Veterans. As applicable, each grantee's performance will be indicated by how they meet targets relevant to the proposed special need population such as permanent housing, negative exits, or employment. Specific targets are identified in the Required Minimum Performance Metrics/Targets section of the NOFO.

Applicants agree to meet the applicable requirements of 38 CFR part 61 as a part of the effort to end homelessness among the Nation's Veterans. Applicants agree to meet the applicable requirements of 2 CFR part 200 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards) as part of the Governmentwide initiative to administer Federal financial assistance systematically and uniformly. In addition, all applicants must offer a low barrier, harm reduction approach that applies Housing First principles to

engaging unsheltered Veterans in services and must have policies and procedures for maintaining low barriers and high-quality engagement through the provision of service.

Required Minimum Performance Metrics/Targets

Applicants for renewal funding must address the needs of the same homeless Veteran special need population identified in the previous special need application and approved in the grant agreement effective October 1, 2021, or in a subsequently approved change of scope. Changes to the special need population are not allowed. Applicants must demonstrate compliance with the special need population requirements in their renewal application and during the grant award period if selected for funding. Refer to 38 CFR 61.41 for additional information on special need populations.

For each of the special need populations below that have Required Minimum Performance Metrics/Targets, the targets are set for the initial funding period of this renewal award starting October 1, 2024. VA may, at its discretion, update these targets at any time, for example during an option year, as applicable. Any new targets will be stated in writing by VA.

- Chronically mentally ill:
  - Discharge to permanent housing target is 60%.
  - Employment of individuals at discharge target is 55%.
  - Negative exits target is less than 20%.
- Frail elderly:
  - Discharge to permanent housing target is 65%.
  - Negative exits target is less than 20%.
- Individuals who care for minor dependents:
  - Discharge to permanent housing target is 70%.
  - Employment of individuals at discharge target is 55%.
  - Negative exits target is less than 20%.
- Terminally ill:
  - Not applicable.
- Women:
  - Discharge to permanent housing target is 70%.
  - Employment of individuals at discharge target is 55%.
  - Negative exits target is less than 20%.

Note that negative exits are defined as those exits from a GPD program for a violation of program rules, failure to comply with program requirements, or leaving the program without consulting staff.

Housing Specifications

The special need beds supported under this grant must be in private rooms with private bathrooms including the following characteristics:

- The minimum square footage for the private bedroom and private bathroom combined is 120 square feet. The bedroom and bathroom do not need to be attached in which case the walkway would not usually count toward the square footage calculation.
- The bathroom must include shower and/or tub, sink, and toilet.
- Neither the bedroom nor the bathroom facilities may be shared (*e.g.,* no shared sink area outside the toilet room).
- Rooms with partial walls are not acceptable. Walls must go floor-to-ceiling. Rooms must have a door and not involve unauthorized passage through another dwelling unit.

Definitions

The regulations for the GPD program, found in 38 CFR part 61, as well as the uniform guidance for grants (2 CFR part 200) contain all detailed definitions, authorities, and requirements pertaining to this program.

Program Authority

Funding applied for under this Notice is authorized by 38 U.S.C. 2011, 2012, 2061. VA established and implemented this statutory authority for the GPD program in 38 CFR part 61. Funds made available under this Notice may be subject to other applicable laws and regulations including those in title 2, Code of Federal Regulations.

Guidance for the Use of Funds

- Funds requested for renewal grant activities must meet the same criteria identified in the original Notice (published March 4, 2021), and available on the GPD website: *https://www.va.gov/homeless/gpd.asp.*
- Funds requested for renewal grant activities must be the same as what was approved under the previously awarded grant agreement, effective October 1, 2021, or in a subsequently approved change of scope.
- VA reserves the right to fund only those projects or portions of projects based on the percentage of use for the VA grant and based on actual need as determined by VA. Those activities deemed outside the scope of this NOFO will not be funded.

II. Award Information

Award Amount

Approximately $5 million per year for 2 years is available for grants under this Notice. The maximum allowable grant size is determined by the number of beds previously awarded and by each applicant's unique per diem rate. Applicants for renewal funding may request up to the number of beds approved under their currently active GPD special need grant (start date October 1, 2021). Applicants may request fewer beds but may not request more.

Award Period

Grants awarded are expected to be for 2 years starting on October 1, 2024. Continuation funding is not guaranteed. VA reserves the right in any year to make adjustments (*e.g.,* to funding levels, bed numbers, services, locations, performance targets, dates) as needed within the intent of the Notice based on a variety of factors including availability of funding and grantee performance.

III. Eligibility Information

Eligible Applicants

To be eligible, an applicant must be one of the 16 currently operational GPD special need grantees who was awarded a grant based on the Notice published in *www.grants.gov* on March 4, 2021, with a project start date of October 1, 2021. A list of active GPD special need grant recipients is available on the GPD website: *https://www.va.gov/homeless/gpd.asp.*

Eligible entities must have an active registration in the System for Award Management (SAM) and must maintain their active status throughout the application period. VA may not make a Federal award to an applicant if the applicant has not complied with all applicable Unique Entity Identifier (UEI) and SAM requirements. Applicants may refer to 2 CFR parts 200, 25, and *www.SAM.gov* for more information.

If an applicant has not fully complied with the SAM and UEI requirements by the time VA is ready to make an award, VA may determine that the applicant is not qualified to receive a Federal award and may use that determination as a basis for making an award to another applicant.

If awarded a grant, applicants must maintain an active SAM account for the duration of the grant period as a continuing condition of eligibility.

GPD grants are ''Federal financial assistance'' as defined in 2 CFR 25.406 and 200.1. Therefore, applicants must answer ''yes'' in *www.SAM.gov* saying they ''wish to apply for a Federal assistance project or program'' under the Financial Assistance Representation and Certification section. Then, applicants

must certify to the representations and certifications in SAM.

Please note that all elements of 2 CFR part 200 apply to any organization that carries out a Federal award as a recipient or subrecipient, including for-profit organizations. This includes the monitoring and the examination of their records.

IV. Cost Sharing

Cost sharing is not required for this grant program.

V. Application and Scoring Information

Content and Form of Application

Applications submitted in response to this NOFO must be submitted through the online electronic grants management system by following the instructions at *https://www.va.gov/homeless/gpd.asp.* See also the Application Submission section of this Notice.

The numbered questions below make up the special need renewal application that all applicants must complete. Applicants must include all required documents in their application submission. Submission of an incorrect, incomplete, inconsistent, unclear, or incorrectly formatted application package may result in the application being rejected.

VA may make a reasonable effort to confirm or clarify information in the application. VA reserves the right to consider ineligible or to not select any application with inconsistent information or information that cannot be readily confirmed or that leads to an unclear understanding of the proposed project.

This Notice cannot predict all potential circumstances. Applicants are expected to propose plans within the requirements and guidance of the NOFO. When a specific situation is not explicitly addressed in the NOFO, applicants must use their judgment to propose plans that meet the intent of the NOFO and may explain how their choices align with the intent. All applications will be evaluated against the requirements and guidance in the NOFO.

Organization Profile (Eligibility)

1. Unique Entity Identifier.
2. Employer Identification Number.
3. Organization Name.
4. Organization Address (including city, state, postal code, and congressional district).
5. Indirect Cost Rate (percentage) and upload a copy of your agency's Federally Negotiated Indirect Cost Rate Agreement (NICRA) that supports this rate or upload a copy of your agency's certification of de minimis indirect cost rate. Note that applicants not requesting indirect costs as described in 2 CFR 200.414 are not required to upload anything here.
6. System for Award Management expiration date. Refer to the Eligible Applicants section of the NOFO and 2 CFR part 25 for more details.

Overview

7. Station number of the VA medical facility whose catchment area includes the proposed area to be served in this application (select one).
8. Veterans Integrated Service Network (select one).
9. Continuum of Care (CoC) (select all that apply).

Application

10. Special need population proposed (must be the same as previously approved for the grant period starting on October 1, 2021. See also related sections of this Notice: Required Minimum Performance Metrics/Targets section and Guidance for the Use of Funds section).
11. Total number of Veteran beds for which your agency is requesting per diem in this application and corresponding budget amounts requested (must be the same or less than previously approved for the grant period starting on October 1, 2021. See also related sections of this Notice: Guidance for the Use of Funds section and Award Amount section).
12. Site address(es): (Note that addresses are expected to be the same as previously approved for the grant period starting on October 1, 2021. If requesting multiple sites within a single application, all sites must fall within the same VA medical facility catchment area.)

a. Complete address, city, state, ZIP code + four-digit extension, county, and congressional district.

b. The total number of all beds and the number of GPD funded beds, per site address.

c. Identify the various demographics that will be served per site address (*i.e.,* men/transgender/non-binary/other, women/transgender/non-binary/other, minor dependents, families, registered sex-offenders, justice involved Veterans, other).

d. Per location, a description of how the facility's participant living space will be configured. Include the square footage of the room, confirmation that each special need bed is in a private room with a private bath, and other details about the private and shared spaces in the facility for these Veterans.

Detailed Application Design

This is the portion of the application that describes the proposed project. Proposed projects must meet the same criteria identified in the original Notice (published March 4, 2021, and available on the GPD website: *https://www.va.gov/homeless/gpd.asp*). For example, starting on page 12 of the original notice is the *Detailed Application Design* section which includes questions for the scored criteria (*i.e.,* Outreach, Project Plan, Ability, Need, and Coordination). Proposed projects are expected to continue the same application design that was approved for the previous grant period starting on October 1, 2021, or in a subsequently approved change of scope, with minimal if any changes.

VA reviewers will score the application based on how the detailed application design addresses the areas of need, outreach, project plan, ability, and coordination in relation to the selected special need population. These sections are in compliance with 38 CFR part 61.

Need

13. In approximately 250 words or less, applicants must state that the responses to the 2 *Need* questions from their previous application submitted in 2021 remain the same or must provide an updated response. See original Notice page 15, #27–28.

Outreach

14. In approximately 250 words or less, applicants must state that the response to the 1 *Outreach* question from their previous application submitted in 2021 remains the same or must provide an updated response. See original Notice page 13, #18.

Project Plan

15. In approximately 250 words or less, applicants must state that the responses to the 5 *Project Plan* questions from their previous application submitted in 2021 remain the same or must provide an updated response. See original Notice pages 13–14, #19–23.
16. Complete the table listing all the supportive services that will be provided to Veterans in the project (see Example 1). Applicants are expected to continue the same services that were approved for the previous grant period starting on October 1, 2021, or approved in a subsequent change of scope, with minimal changes, if any. Successful applicants will be allowed to exceed the minimum standards during the grant period without need for written prior approval from the GPD National

Program Office, but they will not be allowed to reduce the standards.

EXAMPLE 1.

Description of service	Minimum frequency	Total hours/month service will be offered for all GPD participants	Mode of engagement	Special need population for which service is available	Job title and minimum credentials required	Service provider
Case Management	Weekly	320 hours (2 full-time equivalents (FTE), 40 hours/week).	In person	Chronically mentally ill	Case Manager; Licensed Clinical Social Worker or Master of Social Work.	Agency staff.
Legal Services	Monthly	5 hours	Virtual through video.	Chronically mentally ill	Paralegal, Bachelor's	Contractors.
Recreational Therapy	Biweekly	10 hours	Hybrid in person and video.	Chronically mentally ill	Recreation Coordinator, no degree required, lived experience preferred.	Community volunteers.

Ability

17. In approximately 500 words or less, discuss your past performance under the previously awarded special need grant (start date October 1, 2021). At minimum applicants must discuss the performance measures (*e.g.,* exits to permanent housing, employment at exit, negative exits), length of stay in the GPD program by Veterans, occupancy rates of the GPD awarded beds, and use of private rooms with private bathrooms.

18. Complete the staffing plan table section of the application for this project (see Example 2). Applicants are expected to continue the same staffing plan that was approved for the previous grant period starting on October 1, 2021, or in a subsequently approved change of scope, with minimal if any changes. New or updated position descriptions for up to four key positions may be attached. Do not attach previously submitted position descriptions. Do not attach resumes. Successful applicants will be allowed to exceed the minimum standards during the grant period without the need for written prior approval from the GPD National Program Office, but they will not be allowed to reduce the standards.

EXAMPLE 2.

Job title (do not name specific names) (agency, contractors, sub-contractors)	Brief (1–2 sentences) description of responsibilities	Minimum required educational level	Hours per week allocated to the GPD project (40 hours equals full-time)	Number of FTEs	Amount of annual salary allocated to the GPD project per year	Amount of salary, per job title, for the FTE position(s) per year
Case manager	Responsible for working with the Veteran to develop and monitor an individual service plan and to adjust the plan as needed. Coordinates support with other community agencies..	Bachelor's degree.	60 hours	1.5	$90,000	$60,000

19. In approximately 250 words or less, applicants must state that the responses to the 3 *Ability* questions from their previous application submitted in 2021 remain the same or must provide an updated response. See original Notice page 14–15, #24–26.

Coordination

20. In approximately 250 words or less, applicants must state that the responses to the 2 *Coordination* questions from their previous application submitted in 2021 remain the same or must provide an updated response. See original Notice page 15, #29–30. New or updated letters of coordination may be attached. Do not attach previously submitted letters of coordination.

Note that VA reserves the right to confirm with local VA medical facility staff or others any information related to an application. If information cannot be confirmed or if discrepancies are identified, VA reserves the right to adjust award decisions, to not select the application, to consider other application(s) in rank order, or to make other remedies as appropriate.

Organizational Leadership

21. Complete the organization leadership table. At minimum, this table must include the positions with the following titles or equivalent titles: Executive Director, Chief Financial Officer, and Project Manager. The table also must include a complete list of the current Board of Directors. For each position include name, title, phone number, and email address. See also Conflicts of Interest section.

EXAMPLE 3.

Name	Title	Phone number	Email address
Thi Nguyen	Executive Director	111–222–3333	*email@address.org.*
Anisa Osman	Chief Financial Officer	111–222–3333	*email@address.org.*
Marco Aguilar	Project Officer	111–222–3333	*email@address.org.*
Angel Banmeke	Chair, Board of Directors	111–222–3333	*email@address.org.*
Lei Yang	Treasurer, Board of Directors	111–222–3333	*email@address.org.*

External Attachments

Applications that do not consist of all required documents will be considered incomplete.

When submitting an attachment in spreadsheet or table format, applicants are encouraged to convert to portable document format (PDF) prior to submission. Applicants who submit materials in PDF are encouraged to submit a native PDF (*i.e.,* a machine-readable PDF, not an image only or scanned PDF), if possible.

1. SF–424 Application for Federal Assistance (required).

a. The form may be downloaded from the program website at *https://www.va.gov/homeless/gpd.asp* or at *https://www.grants.gov/forms/forms-repository/sf-424-family.*

b. The SF–424 must be signed by a person at the applicant organization who is authorized to make legal commitments on behalf of the organization.

c. The signature on the SF–424 must be digital or wet-ink signature. A blank signature field or a ''signature'' that is manually typed will not be accepted. VA reserves the right to communicate with an applicant, as needed, prior to making threshold decisions.

d. A signature on the SF–424 indicates the applicant agrees to comply with all SF–424B Non-Construction Assurances and terms and conditions of award. Applicants do not need to submit the SF–424B with the application. Instead, the applicant agrees to the assurances by maintaining an active registration in SAM. Refer to the Eligibility section for how to complete the Federal financial assistance representation and certification section in SAM. For awareness, applicants may refer to the GPD website for a list of assurances and for a sample standard terms and conditions of award.

2. Updated NICRA or certification of de minimis indirect cost rate (if needed).

3. Updated letter(s) of coordination (optional).

4. Updated position descriptions (optional).

5. Other (optional).

Required Certifications

By signing and submitting this application for Federal assistance, I agree to the following:

1. The applicant commits to all certifications from the previous special need Notice (dated March 4, 2021).

2. The applicant organization commits to implementing a low barrier approach to providing services to Veterans which generally means service occurs on the same day from the point of identification or referral to the GPD project or within no more than 72 hours.

3. The applicant commits to engaging in the local coordinated entry process and the by-name list, as appropriate.

4. The applicant commits to providing supportive housing beds in private rooms with private bathrooms and to meeting the housing specifications in the NOFO.

5. The applicant commits to having written standard operating procedures on conflicts of interest (see Conflicts of Interest section).

6. No more than 25% of the awarded beds for adult participants will be occupied by people not being served by the GPD grant.

7. The applicant commits to monitoring their actual grant costs compared to requested costs at least quarterly and commits to submitting a revised per diem rate request immediately, when needed, to prevent improper accumulation of unobligated funds.

8. The applicant commits to ensuring staff supported by grant funds are trained annually regarding suicide prevention and commits to having written standard operating procedures on suicide prevention developed in consultation with the local VA medical facility.

9. The applicant commits to ensuring staff supported by grant funds are trained annually regarding equity and inclusion and commits to having written standard operating procedures on nondiscrimination of any individuals based on factors including but not limited to race, color, religion, sex, gender identity, gender expression, sex characteristics, sexual orientation, pregnancy, national origin, disability, age, genetic information, marital status, parental status, or political affiliation.

10. Generally, infrastructure costs are not allowed under GPD transitional housing grants, however, the applicant acknowledges that if the budget includes construction costs, VA prior approval is needed for such costs and the requirements of the Build America Buy America Act (Pub. L. 117–58) apply to the applicant and to all subrecipients and contractors.

11. The applicant organization commits to complying with all applicable requirements for the grant including, but not limited to, 38 CFR part 61, 2 CFR part 200, Federal cost principles, terms and conditions of award, requirements in the NOFO, performance measures, and reporting requirements.

12. The applicant does not have any past due SF–425 Federal Financial Report (FFR) or any other outstanding requirement under any GPD grant.

13. If the applicant organization is the recipient of an historical GPD capital grant (*i.e.,* a capital grant awarded in fiscal year 2020 or before) with an ongoing period of obligation associated with the facility used for special need grant services, then the applicant commits to submitting a strongly competitive application for this special need renewal opportunity. The applicant commits to maintaining bed numbers and occupancy levels. The applicant commits this at least until the expiration of the period during which VA could seek recovery under 38 CFR 61.67. Failure to do so may result in an immediate partial capital grant repayment.

VI. Application Review Information

VA has instituted procedures for assessing the technical merit of applications to provide for an objective review of applications and to assist you in understanding the standards against which your application will be scored. Reviewers will award points based on the evaluation criteria described in 38 CFR 61.40(b) as summarized below.

Criterion	Points (maximum)
1. Need	150
2. Outreach	100
3. Project Plan	300
4. Ability	200
5. Coordination	200
6. Completion Confidence	50
Total	1,000

VII. Merit Review and Selection Process

A technical merit review panel will carefully evaluate applications against the criteria to determine the merit of applications. Up to 1,000 points may be awarded to an applicant depending on the quality of responses provided. The final scores will serve as the primary basis for selection of applications for funding. The grant review panel will follow 38 CFR part 61 and the Uniform Guidance on application grant review (pursuant to 2 CFR part 200). VA may use information such as historical program documents of past performance, both VA and non-VA, including those from other Federal, state, and local agencies as well as audits by private or public entities in determining scores. The grant review panel will be instructed to consider past performance (*e.g.,* performance metrics, lengths of stay, occupancy rates, use of

private rooms with private bathrooms) when scoring applications. The panel results are advisory in nature and not binding on the Grant Program Officer.

Depending on factors such as the quantity and quality of applications received, the availability of funding, and past performance, VA reserves the right to make additional rounds of conditional selections from this NOFO, to reduce the amount of funding or beds awarded, or to take other actions as appropriate. VA reserves the right to negotiate with applicants as needed to accomplish the overall goals and objective of the Notice.

VIII. Risk Assessment

Prior to making an award, and at any time post-award, VA will review information available through various sources, including its own records and any Office of Management and Budget-designated repository of Governmentwide eligibility qualification or financial integrity information, such as *www.SAM.gov.*

In addition, VA will comply with the requirements of 2 CFR part 180, supplemented by 2 CFR part 801 (Non-procurement Debarment and Suspension). This risk evaluation may incorporate results of the evaluation of the applicant's eligibility (threshold review) or the quality of its application (merit review). If VA determines that an award will be made, specific conditions that correspond to the degree of risk assessed may be applied to the award. VA will conduct a business risk assessment in accordance with 2 CFR 200.206. Applicants or grantees may be asked to submit additional information for VA to assess the adequacy of their financial management of Federal funds.

IX. Award Administration Information

Award Notices

Although subject to change, VA expects to announce grant awards by approximately August 2024. VA reserves the right in any year to make adjustments (*e.g.,* to funding levels) as needed within the intent of the NOFO based on a variety of factors, including the availability of funding.

The applicant's signature on the SF–424, including electronic signature, constitutes a binding offer by the applicant and constitutes agreement to the terms and conditions of award. VA may elect to award funds with or without discussions with the applicant. Applicants may review GPD's general terms and conditions of award at any time on the GPD website at *https://www.va.gov/homeless/gpd.asp.*

Only a grant agreement with a VA signature is evidence of an award and is an authorizing document allowing costs to be incurred against a grant award. Other notices, letters, or announcements are not authorizing documents. The grant agreement includes the terms and conditions of award and must be signed by VA to be legally binding.

Administrative and National Policy Requirements

VA places great emphasis on responsibility and accountability. VA has procedures in place to monitor grants provided under this grant program. All applicants selected in response to this NOFO must agree to meet applicable inspection standards outlined in the grant agreement.

Conflicts of Interest

Consistent with 2 CFR 200.112, grantees must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity immediately and no less frequently than annually thereafter.

The conflict-of-interest guidance for general procurement standards (2 CFR 200.318) is hereby applied to other grant actions beyond procurement actions. Specifically, grantees must maintain written standards of conduct covering conflicts of interest and governing the actions of its employees or other personnel engaged in activities funded from the GPD grant, including the selection, award, and administration of contracts. No employee, officer, or agent may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, agent, any member of the immediate family, a partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract. The officers, employees, and agents of the grantee organization may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts. However, grantees may set standards for situations in which the financial interest is not substantial, or the gift is an unsolicited item of nominal value. The standards of conduct must provide for disciplinary actions to be applied for violations of such standards.

Suicide Prevention

Grantees must ensure staff supported by grant funds are trained annually regarding suicide prevention and how to address situations in which Veterans demonstrate suicidal ideation. Standard operating procedures are to be developed on suicide prevention in consultation with the local VA medical facility. VA training is available at *https://www.va.gov/EMPLOYEE EDUCATION/ees_vha_train.asp* and *https://learn.psycharmor.org/courses/va-save.* Suicide Prevention Coordinator locator (for in-person training) is available at *https://www.veteranscrisisline.net/find-resources/local-resources.*

Equity and Inclusion

Grantees must ensure staff supported by grant funds are trained annually regarding equity and inclusion. Standard operating procedures are to be developed on nondiscrimination of any individuals based on factors including but not limited to race, color, religion, sex, gender identity, gender expression, sex characteristics, sexual orientation, pregnancy, national origin, disability, age, genetic information, marital status, parental status, or political affiliation. VA training is available at *https://www.va.gov/EMPLOYEEEDUCATION/ees_vha_train.asp.*

Life Safety Code

Grantees must meet the requirements of the current edition of the Life Safety Code of the National Fire Protection Association as it relates to the specific GPD facility(s). Grantees should note that all facilities must be protected throughout by an approved automatic sprinkler system unless a facility is specifically exempt under the Life Safety Code. Applicants should consider this when submitting their grant applications, as no funds will be made available without meeting these requirements.

Inspections

All units must be reinspected by VA no less frequently than annually. Reinspection of occupied units requires advance planning and must be started early to avoid delays. VA reserves the right to withhold payments, reduce beds, terminate a grant, or take other action as appropriate when inspection or reinspection requirements are delayed or not met.

Payments of Grant Funds

Payment Requests

Grantees will receive payments electronically through the U.S. Department of Health and Human Services (HHS) Payment Management System or other payment method identified by VA. Grantees will have the ability to request payments as frequently as they choose or on a reimbursement

basis as determined by VA, subject to the following limitations:

- During the first quarter of each annual period, the grantee's cumulative request for funds may not exceed 35% of the annual grant amount without VA written prior approval.
- By the end of the second quarter of each annual period, the grantee's cumulative request for funds may not exceed 60% of the annual grant amount without VA written prior approval.
- By the end of the third quarter of each annual period, the grantee's cumulative request for funds may not exceed 80% of the annual grant amount without VA written prior approval.
- By the end of the fourth quarter of each annual period, the grantee's cumulative request for funds may not exceed 100% of the annual grant amount.

Unobligated Balances

If applicable, grantees with unobligated balances may, with approval from the GPD National Program Office, carry forward such unobligated balances. If applicable, at VA's discretion, award amounts may be subject to reductions. Reductions are permanent and not restorable. Reductions will be calculated based on the amount of the unobligated balance shown in HHS' Payment Management System by the third quarter of each year. VA may calculate reductions with or without input from grantees. Grantees are advised to stay current with reimbursements from the payment system in order to avoid the appearance of inaccurately high unobligated balances.

Immediate Cash Needs

VA will make payments to reimburse amounts expended (38 CFR 61.61(b)). Advance payments are not provided to GPD grantees. Grantees must maintain written procedures to minimize the time elapsing between drawing down funds from the Federal Government and disbursing the funds for grant costs. Also, grantees must maintain financial management systems that meet the standards for fund control and accountability as established in 2 CFR 200.305. Payments drawn must be limited to the minimum amounts needed and be timed in accordance with actual and immediate cash requirements of the grantee in carrying out the purpose of the approved project. The timing and amount of payments must be as close as is administratively feasible to the actual disbursements by the grantee for direct project costs and the proportionate share of any allowable indirect costs. Typically, ''immediate'' means within 3 business days, as articulated by HHS: *https://pms.psc.gov/grant-recipients/funding-request-formula.html.*

Per-Item Cost Documentation

- Grantees must support their request for payments with adequate fiscal documentation, including program income and expenses.
- Grantees are advised to keep careful records, including documentation of voluntary leveraged funding from other sources and including cost calculations, such as itemized invoices and cost reasonableness.
- Grantees must submit properly prepared and fully documented vouchers within 30 days after the end of each month. Grantees who are unsure if their submission is properly prepared and fully documented should submit early to allow time for review and resubmission no later than 30 days after the end of each month.
- Per 38 CFR 61.44, at the time of NOFO publication, payment will be either the daily cost of care minus other sources of income or two times the current VA State Home per diem rate for domiciliary care, whichever is less. Grantees should be aware that special need awards are subject to funds availability. Therefore, in the event of a funding shortfall, VA will notify grantees of any applicable revised (lower) maximum rate.
- The per diem payment calculation may be found at 38 CFR 61.44 and current maximum per diem rates are available on the GPD provider website at *https://www.va.gov/HOMELESS/GPD_ProviderWebsite.asp.*

Reporting and Monitoring

VA will oversee and monitor the services provided to the participants by the grantee. Monitoring will include financial reviews and performance. All grantees are subject to audits conducted by VA or its representative. See 2 CFR 200.337 regarding Access to Records. The grantee will be expected to demonstrate adherence to the grantee's proposed program concept, as described in the application. The reporting requirements and monitoring cadence (bi-weekly, monthly, quarterly, or annually) will be determined in part based on VA's pre-award and post-award risk assessment.

Reporting

- An annual SF–425 FFR is required to be submitted no later than 120 days after the end of each grant year (no later than January 31). Grantees who do not submit on time are subject to being withheld from receiving payments temporarily pending receipt of the report. An FFR form is available on the GPD provider website at *https://www.va.gov/HOMELESS/GPD_ProviderWebsite.asp* or at *www.grants.gov.* Instructions for submission also are on the GPD provider website.
- At a minimum, a quarterly review of each GPD grantee's progress toward meeting performance goals is required, as applicable. The targets are set for the initial funding period of this renewal award, starting October 1, 2024. VA may, at its discretion, update these targets any time, for example during an option year, as applicable. Any new targets will be stated in writing by VA. Applicants should be aware that bed utilization rates can impact funding decisions during the award period.
- Annual reporting may involve certifying to VA that certain requirements are complete including, but is not limited to:
  - Updated leadership information, such as contact information for the Board of Directors and Executive Officers, is provided.
  - An updated NICRA or certification of de minimis indirect cost rate is provided (if needed).
  - Organizational records in SAM are complete, including:
    - The organizational registration is active.
    - The Federal financial assistance representation and certification section is complete.
    - No organization or person involved in the grant has an active exclusion.
  - Any conflicts of interest have been disclosed immediately and annually thereafter.
  - Annual training for staff regarding suicide prevention is complete.
  - Annual training for staff regarding equity and inclusion is complete.
  - All required SF–425 FFRs have been submitted to VA for all GPD grants. All future FFRs will be submitted on or before the due date.
  - The organization is up to date on any actions required by an A–133 Single Audit or a VA-specific fiscal review (*e.g.,* a fiscal review of GPD or other VA grants conducted by VA's Office of Business Oversight).
  - The organization does not have an outstanding GPD, VA, or Federal debt.
  - The organization continues to meet the management standards described in 2 CFR part 200 and 38 CFR part 61 and continues to be able to effectively implement statutory, regulatory, and other requirements imposed on grantees (per requirements such as 2 CFR 200.206(b)(2)).

○ An updated per diem rate request reflecting current costs has been submitted (if needed).

• If additional time or funding becomes available, grantees will be notified about how to make a request (notwithstanding 38 CFR 61.61(b) and in compliance with 2 CFR 200.308(c) and § 200.309).

Closeout

• A final SF–425 FFR is due within 120 days after the grant end date. Grantees who do not comply are subject to public reporting on the Federal websites, such as SAM, for material failure to comply with the terms of the award (per 2 CFR 200.344).

• Grantees must promptly refund any balances of unobligated funding that are not authorized to be retained. Any funds paid to the grantee in excess of the amount to which the grantee is finally determined to be entitled under the terms of the Federal award constitute a debt to the Federal Government (2 CFR 200.346).

Monitoring

• Each project receiving special need funding will have a liaison appointed from a nearby VA medical facility to provide oversight and to monitor services provided to Veterans experiencing homelessness.

• It is expected that Veterans will transition to permanent housing as rapidly as clinically appropriate based on individual needs. A typical length of stay, on average, generally is within 6–12 months (or less depending on the population) and not to exceed 24 months. Grantees must work closely with Veterans to support timely transitions to permanent housing.

• Grantees may not make significant changes to a project after a grant is awarded without written prior approval from the GPD National Program Office.

• VA reserves the right to disallow services provided by the grantee if VA determines that they are of unacceptable quality, in which case grant funds may not be used to pay for them.

• Poor performance, such as low bed utilization, may result in bed reductions and may impact future funding or option year(s) decisions.

Record Retention

Grantees must follow Federal guidelines on record retention which require that grantees maintain and provide access to all records pertaining to grant activities for a period of at least 3 years from the date of submission of the final expenditure report. See 2 CFR 200.334–338 for more specific information, including information about the start of the record retention period for awards that are renewed quarterly or annually and when the records must be retained for more than 3 years.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on January 29, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2024–02057 Filed 2–1–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Friday,
No. 23 February 2, 2024

Part II

Department of Homeland Security

8 CFR Part 214
Improving the H–1B Registration Selection Process and Program Integrity; Final Rule

DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 214

[CIS No. 2766–24; DHS Docket No. USCIS–2023–0005]

RIN 1615–AC70

Improving the H–1B Registration Selection Process and Program Integrity

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Final rulemaking.

SUMMARY: The U.S. Department of Homeland Security (DHS) is amending its regulations to implement the proposed beneficiary centric selection process for H–1B registrations, provide start date flexibility for certain H–1B cap-subject petitions, and implement additional integrity measures related to H–1B registration.

DATES: This final rule is effective March 4, 2024.

FOR FURTHER INFORMATION CONTACT: Charles L. Nimick, Chief, Business and Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, U.S. Department of Homeland Security, 5900 Capital Gateway Drive, Camp Springs, MD 20746; telephone (240) 721–3000.

SUPPLEMENTARY INFORMATION:

Table of Contents

Table of Abbreviations

CFR—Code of Federal Regulations
CPI–U—Consumer Price Index for All Urban Consumers
DHS—U.S. Department of Homeland Security
DOL—U.S. Department of Labor
FR—Federal Register
FY—Fiscal Year
HR—Human Resources
HSA—Homeland Security Act of 2002
IMMACT 90—Immigration Act of 1990
INA—Immigration and Nationality Act
LCA—Labor Condition Application
NEPA—National Environmental Policy Act
NPRM—Notice of Proposed Rulemaking
OMB—Office of Management and Budget
PRA—Paperwork Reduction Act
PRD—Policy Research Division
Pub. L.—Public Law
RFA—Regulatory Flexibility Act of 1980
RIA—Regulatory Impact Analysis
Stat.—U.S. Statutes at Large
TLC—Temporary Labor Certification
UMRA—Unfunded Mandates Reform Act
U.S.C.—United States Code
USCIS—U.S. Citizenship and Immigration Services

I. Executive Summary

DHS is amending its regulations relating to the H–1B registration selection process. This final rule implements a beneficiary centric selection process for H–1B registrations, start date flexibility for certain H–1B cap-subject petitions, and integrity measures related to H–1B registration. These provisions are being codified at new 8 CFR 214.2(h)(8)(iii)(A), (h)(8)(iii)(D), (h)(8)(iii)(E), (h)(10)(ii), (h)(10)(iii), and (h)(11)(iii)(A). At this time, DHS is not finalizing other provisions of the ''Modernizing H–1B Requirements, Providing Flexibility in the F–1 Program, and Program Improvements Affecting Other Nonimmigrant Workers,'' Notice of Proposed Rulemaking (NPRM), published in the **Federal Register** on October 23, 2023 (October 23 NPRM).

A. Purpose and Summary of the Regulatory Action

The purpose of this rulemaking is to improve the H–1B registration selection process. Through this rule, DHS is implementing a beneficiary centric selection process for H–1B registrations. Instead of selecting by registration, U.S. Citizenship and Immigration Services (USCIS) will select registrations by unique beneficiary. Each unique beneficiary who has a registration submitted on their behalf will be entered into the selection process once, regardless of how many registrations are submitted on their behalf. If a beneficiary is selected, each registrant that submitted a registration on that beneficiary's behalf will be notified of the beneficiary's selection and will be eligible to file a petition on that beneficiary's behalf during the applicable petition filing period. *See* new 8 CFR 214.2(h)(8)(iii)(A)(*1*) and (*4*). DHS anticipates that changing to a beneficiary centric selection process for H–1B registrations will reduce the potential for gaming the process to increase chances for selection and help ensure that each beneficiary has the same chance of being selected, regardless of how many registrations are submitted on their behalf.

DHS will also provide start date flexibility for certain H–1B cap-subject petitions. DHS is clarifying the requirements regarding the requested employment start date on H–1B cap-subject petitions to permit filing with requested start dates that are after October 1 of the relevant fiscal year, consistent with current USCIS policy, by removing the current regulatory text at 8 CFR 214.2(h)(8)(iii)(A)(*4*).

Additionally, DHS is implementing integrity measures related to the H–1B registration process, including requiring registrations to include the beneficiary's valid passport information or valid travel document information, and prohibiting a beneficiary from being registered under more than one passport or travel document. *See* new 8 CFR 214.2(h)(8)(iii)(A)(*4*). DHS is also codifying USCIS' ability to deny H–1B petitions or revoke an approved H–1B petition where: there is a change in the beneficiary's identifying information from the identifying information as stated in the registration to the

information as stated in the petition; the underlying registration contained a false attestation or was otherwise invalid; the registration fee was invalid; or where the H–1B cap-subject petition was not based on a valid registration. *See* new 8 CFR 214.2(h)(8)(iii)(A) and (D). In addition, DHS is also further codifying USCIS' authority to deny an H petition where the statements on the petition, H–1B registration, labor condition application (LCA), or temporary labor certification (TLC), as applicable, were inaccurate, fraudulent, or misrepresented a material fact, including if the attestations on the H–1B registration are determined to be false. *See* new 8 CFR 214.2(h)(10)(ii)–(iii). Finally, DHS is codifying USCIS' ability to revoke an approved H petition where the statements on the petition, H–1B registration, TLC, or the LCA, as applicable, were inaccurate, fraudulent, or misrepresented a material fact, including if the attestations on the H–1B registration are determined to be false. *See* new 8 CFR 214.2(h)(11)(iii)(A).

B. Summary of Costs and Benefits

The purpose of this rulemaking is to improve the H–1B registration selection process. For the 10-year period of analysis of the final rule, DHS estimates the annualized net cost savings of this rulemaking will be $2,199,374 annualized at 3 percent and 7 percent. Table 1 provides a more detailed summary of the final rule provisions and their impacts.

C. Summary of Changes From the Notice of Proposed Rulemaking

Following careful consideration of public comments received, this final rule adopts some of the provisions proposed in the October 23 NPRM, with some changes as described below.

Passport or Travel Document Requirement

DHS will make a modification to the proposed passport requirement to specify that registrations must include the beneficiary's valid passport or valid travel document. *See* new 8 CFR 214.2(h)(8)(iii)(A)(*4*)(*ii*) and (D)(*1*). As proposed in the NPRM, 8 CFR 214.2(h)(8)(iii)(A)(*4*)(*ii*) would have required the registration to include the beneficiary's valid passport information and would not have provided an exception to the passport requirement. However, after considering public comments expressing concern for stateless individuals, refugees, and others who are unable to obtain valid passports, DHS has decided to modify new 8 CFR 214.2(h)(8)(iii)(A)(*4*)(*ii*) so that the registration must include the beneficiary's valid passport information or valid travel document information. Requiring the beneficiary's valid passport information or valid travel document information at the registration stage would align with the current Form I–129 which asks for the beneficiary's ''passport or travel document.'' This modification to allow for a valid travel document is intended to narrowly accommodate stateless individuals, refugees, and others who are unable to obtain valid passports, and is directly in response to public comments expressing concerns for these populations. The travel document must be the travel document that the beneficiary, if or when abroad, intends to use to enter the United States if issued an H–1B visa. *See* new 8 CFR 214.2(h)(8)(iii)(A)(*4*)(*ii*). Therefore, the travel document must be valid for the entry of the bearer into the United States. An example of a valid travel document includes one of the travel documents listed in the Department of State's reciprocity schedule.[1] DHS is also modifying this provision by adding ''or when'' to the phrase ''if abroad.'' This modification is intended to clarify that the passport or travel document must be the same passport or travel document that the beneficiary intends to use to enter the United States, whether the beneficiary is abroad at time of registration or in the United States at the time of registration and will subsequently depart to obtain an H–1B visa and return to the United States to request admission as an H–1B nonimmigrant.

Under new 8 CFR 214.2(h)(8)(iii)(A)(*4*)(*ii*), each beneficiary may only be registered under one passport or travel document. Under new 8 CFR 214.2(h)(8)(iii)(A)(*2*), if USCIS determines that registrations are submitted by either the same or different prospective petitioners for the same beneficiary, but using different identifying information, USCIS may find those registrations invalid and deny or revoke the approval of any H–1B petition filed based on those registrations. Additionally, any H–1B petition filed on behalf of a beneficiary must contain and be supported by the same identifying information provided in the selected registration, and petitioners must submit evidence of the passport or travel document used at the time of registration to identify the beneficiary under new 8 CFR 214.2(h)(8)(iii)(D)(*1*). Such evidence may include a copy of the passport or travel document, consistent with current practice. In its discretion, USCIS may find that a change in identifying information in some circumstances would be permissible. Such circumstances could include, but are not limited to, a legal name change due to marriage, change in gender identity, or a change in passport number or expiration date due to renewal or replacement of a stolen passport, in between the time of registration and filing the petition. USCIS may deny or revoke an H–1B petition that does not meet these requirements. *See* new 8 CFR 214.2(h)(8)(iii)(D)(*1*).

Multiple Registrations by Related Entities

DHS will not finalize the proposed change at 8 CFR 214.2(h)(2)(i)(G) to prohibit related entities from submitting multiple registrations for the same individual at this time. DHS will address and may finalize this proposed provision in a subsequent final rule. However, the submission of multiple registrations for the same individual by related entities should not increase the chances of selection given the finalization of the proposal to have USCIS select registrations by unique beneficiary. *See* new 8 CFR 214.2(h)(8)(iii)(A)(*1*) and (*4*).

Severability

DHS is adding new regulatory text on severability at 8 CFR 214.2(h)(8)(v)(B) and redesignating the severability clause at paragraph (h)(8)(v) as new paragraph (h)(8)(v)(A). While severability was discussed in the NPRM, it was only discussed in the preamble and there was no proposed regulatory text.

Other Changes From the NPRM

DHS is also amending the proposed regulatory text at 8 CFR 214.2(h)(8)(iii)(A)(*4*) to state, ''A petitioner may file an H–1B cap-subject petition on behalf of a registered beneficiary only after their properly submitted registration for that beneficiary has been selected for that fiscal year.'' The only change from the NPRM is changing ''a'' to ''their'' before ''properly submitted registration.'' DHS is making this change to eliminate any confusion that the petitioner listed on the H–1B petition must be the same as, or a successor in interest to, the prospective petitioner listed on the registration that was selected.

[1] The Department of State website shows visa reciprocity by country. To view the Reciprocity Page for a country of nationality, select the country/area of authority from the list of countries on the left side menu. On the country's Reciprocity Page, select ''Passports & Other Travel Documents.'' Department of State, U.S. Visa: Reciprocity and Civil Documents by Country, *https://travel.state.gov/content/travel/en/us-visas/Visa-Reciprocity-and-Civil-Documents-by-Country.html.*

II. Background

A. Legal Authority

The Secretary of Homeland Security's authority for these regulatory amendments is found in various sections of the Immigration and Nationality Act (INA or the Act), 8 U.S.C. 1101 *et seq.,* and the Homeland Security Act of 2002 (HSA), Pub. L. 107–296, 116 Stat. 2135, 6 U.S.C. 101 *et seq.* General authority for issuing this rule is found in section 103(a) of the INA, 8 U.S.C. 1103(a), which authorizes the Secretary to administer and enforce the immigration and nationality laws and establish such regulations as the Secretary deems necessary for carrying out such authority, as well as section 102 of the HSA, 6 U.S.C. 112, which vests all of the functions of DHS in the Secretary and authorizes the Secretary to issue regulations.[2] Further authority for these regulatory amendments is found in:

- Section 101(a)(15) of the INA, 8 U.S.C. 1101(a)(15), which establishes classifications for noncitizens who are coming temporarily to the United States as nonimmigrants, including the H–1B classification, *see* INA sec. 101(a)(15)(H)(i)(b), 8 U.S.C. 1101(a)(15)(H)(i)(b);
- Section 214(a)(1) of the INA, 8 U.S.C. 1184(a)(1), which authorizes the Secretary to prescribe, by regulation, the time and conditions of the admission of nonimmigrants;
- Section 214(c) of the INA, 8 U.S.C. 1184(c), which, *inter alia,* authorizes the Secretary to prescribe how an importing employer may petition for nonimmigrant workers, including certain nonimmigrants described at sections 101(a)(15)(H), (L), (O), and (P), 8 U.S.C. 1101(a)(15)(H), (L), (O), and (P); the information that an importing employer must provide in the petition; and certain fees that are required for certain nonimmigrant petitions;
- Section 214(g) of the INA, 8 U.S.C. 1184(g), which, *inter alia,* prescribes the H–1B numerical limitations, various exceptions to those limitations, and the period of authorized admission for H–1B nonimmigrants;
- Section 235(d)(3) of the INA, 8 U.S.C. 1225(d)(3), which authorizes ''any immigration officer'' ''to administer oaths and to take and consider evidence of or from any person touching the privilege of any alien or person he believes or suspects to be an alien to enter, reenter, transit through, or reside in the United States or concerning any matter which is material and relevant to the enforcement of [the INA] and the administration of [DHS]'';
- Section 287(b) of the INA, 8 U.S.C. 1357(b), which authorizes the taking and consideration of evidence ''concerning any matter which is material or relevant to the enforcement of the [INA] and the administration of [DHS]'';
- Section 402 of the HSA, 6 U.S.C. 202, which charges the Secretary with ''[e]stablishing and administering rules . . . governing the granting of visas or other forms of permission . . . to enter the United States'' and ''[e]stablishing national immigration enforcement policies and priorities''; *see also* HSA sec. 428, 6 U.S.C. 236; and
- Section 451(a)(3) and (b) of the HSA, 6 U.S.C. 271(a)(3) and (b), transferring to USCIS the authority to adjudicate petitions for nonimmigrant status, establish policies for performing that function, and set national immigration services policies and priorities.

B. Background on H–1B Registration

The H–1B nonimmigrant visa program allows U.S. employers to temporarily employ foreign workers in specialty occupations, defined by statute as occupations that require the theoretical and practical application of a body of highly specialized knowledge and a bachelor's or higher degree in the specific specialty, or its equivalent. *See* INA secs. 101(a)(15)(H)(i)(b) and 214(i), 8 U.S.C 1101(a)(15)(H)(i)(b) and 1184(i). Through the Immigration Act of 1990 (Pub. L. 101–649), Congress set the current annual cap for the H–1B visa category at 65,000,[3] which limited the number of beneficiaries who may be issued an initial H–1B visa or otherwise provided initial H–1B status each fiscal year.[4] Congress provided an exemption from the numerical limits in INA sec. 214(g)(1)(A), 8 U.S.C. 1184(g)(1)(A), for 20,000 initial H–1B visas, or grants of initial H–1B status, each fiscal year for foreign nationals who have earned a master's or higher degree from a U.S. institution of higher education (''advanced degree exemption'').[5]

To manage the annual cap, USCIS used a random selection process in years of high demand to determine which petitions were selected toward the projected number of petitions needed to reach the annual H–1B numerical allocations. In order to better manage the selection process, DHS created a registration requirement for H–1B cap-subject petitions, which was first implemented in 2020 for the FY 2021 cap season. Through issuance of a final rule in 2019, ''Registration Requirement for Petitioners Seeking To File H–1B Petitions on Behalf of Cap-Subject Aliens,'' DHS developed a new way to administer the H–1B cap selection process to streamline processing and provide overall cost savings to employers seeking to file H–1B cap-subject petitions. *See* 84 FR 888 (Jan. 31, 2019). Under this process, prospective petitioners (also known as registrants) that seek to employ H–1B cap-subject workers must complete a registration process that requires only basic information about the prospective petitioner and each requested worker. The H–1B selection process is then run on properly submitted electronic registrations. Only those with valid selected registrations are eligible to file H–1B cap-subject petitions. 8 CFR 214.2(h)(8)(iii)(A)(*1*).

C. The Need for Regulatory Action

DHS has seen an increase in the number of beneficiaries with multiple registrations submitted on their behalf, as well as an increase in the number and percentage of registrations submitted for beneficiaries with multiple registrations. Under current regulations, there is no limit on the number of registrations that may be submitted on behalf of one unique individual by different registrants. DHS has a strong interest in ensuring that the annual numerical allocations are going to petitioners that truly intend to employ an H–1B worker, rather than prospective petitioners using the registration system as a placeholder for the possibility that they may want to employ an H–1B worker or as a way to game the selection process. *See* 88 FR

[2] Although several provisions of the INA discussed in this NPRM refer exclusively to the ''Attorney General,'' such provisions are now to be read as referring to the Secretary of Homeland Security by operation of the HSA. *See* 6 U.S.C. 202(3), 251, 271(b), 542 note, 557; 8 U.S.C. 1103(a)(1), (g), 1551 note; *Nielsen* v. *Preap,* 139 S. Ct. 954, 959 n.2 (2019).

[3] Up to 6,800 visas are set aside from the 65,000 each fiscal year for the H–1B1 visa program under terms of the legislation implementing the U.S.-Chile and U.S.-Singapore free trade agreements. *See* INA secs. 101(a)(15)(H)(i)(b1), 214(g)(8), 8 U.S.C. 1101(a)(15)(H)(i)(b1), 1184(g)(8).

[4] The 65,000 annual H–1B numerical limitation was increased for FYs 1999–2003. *See* INA sec. 214(g)(1)(A), 8 U.S.C. 1184(g)(1)(A), as amended by section 411 of the ACWIA, Public Law 105–277, div. C, tit. IV, 112 Stat. 2681, and the American Competitiveness in the Twenty-first Century Act of 2000 (AC21), Public Law 106–313, 114 Stat. 1251, as amended by the 21st Century Department of Justice Appropriations Authorization Act, Public Law 107–273, 116 Stat. 1758 (2002). Subsequent to IMMACT 90, Congress also created several exemptions from the 65,000 numerical limitation. *See* INA sec. 214(g)(5), 8 U.S.C. 1184(g)(5).

[5] *See* INA sec. 214(g)(5)(C), 8 U.S.C. 1184(g)(5)(C). This rule also may refer to the 20,000 exemptions under section 214(g)(5)(C) from the H–1B regular cap as the ''advanced degree exemption allocation,'' or ''advanced degree exemption numerical limitation.''

72870, 72897 (Oct. 23, 2023). As a result, DHS has determined that structurally limiting the ability to game the system through beneficiary centric selection will promote the purpose of fair and orderly administration of the annual H–1B numerical allocations.

D. Final Rule and Implementation

On October 23, 2023, DHS published an NPRM, ''Modernizing H–1B Requirements, Providing Flexibility in the F–1 Program, and Program Improvements Affecting Other Nonimmigrant Workers,'' 88 FR 72870. In the October 23 NPRM, DHS stated that it may publish one or more final rules to codify the proposed provisions after carefully considering public comments, and that it may do so in time for the FY 2025 cap season. DHS received 1,315 comments on the NPRM, most of which are substantive. Based on recent program experience and careful review of public comments expressing the urgent need to reform the registration system and support for the proposed beneficiary centric selection process, DHS has decided to first finalize changes to the H–1B registration selection process and other related changes discussed below, to urgently address the potential for abuse of the H–1B registration process, including for the upcoming FY2025 cap season. DHS continues to consider the suggestions made in public comments received on the other proposed changes included in the October 23 NPRM and plans to issue a separate final rule to codify or otherwise address those proposed changes.

III. Public Comments on the Proposed Rule

A. Summary of Public Comments

In response to the proposed rule, DHS received 1,315 comments during the 60-day public comment period. Of these, 510 comments were related to H–1B registration and the related topics that DHS is finalizing through this rulemaking. Of these, 25 comments were duplicate submissions and approximately 78 were letters submitted through mass mailing campaigns. DHS considered all of these comment submissions. Commenters included individuals (including U.S. workers), companies, law firms, a federation of labor organizations, professional organizations, advocacy groups, nonprofit organizations, representatives from Congress and local governments, universities, and trade and business associations. Most commenters expressed support for the rule or offered suggestions for improvement. Of the commenters opposing the rule, many commenters expressed opposition to a part of or all of the proposed rule. Some just expressed general opposition to the rule without suggestions for improvement. For many of the public comments, DHS could not ascertain whether the commenter supported or opposed the proposed rule.

DHS has reviewed all of the public comments received in response to the proposed rule. In this final rule, DHS is only responding to public comments that are related to H–1B registration and the related topics that DHS is finalizing through this final rule. DHS's responses are grouped by subject area, with a focus on the most common issues and suggestions raised by commenters.

B. Statutory and Legal Issues Related to Registration and Background

1. DHS/USCIS Legal Authority Related to Registration

Comment: While providing feedback on the proposed changes to the H–1B selection process, a couple of commenters wrote that centering the selection process around beneficiaries is a proper exercise of DHS's authority under the INA. Citing INA sec. 214(g)(3) and *Walker Macy LLC* v. *USCIS,* 243 F. Supp. 3d 1156 (D. Or. 2017), the commenters wrote that the statutory ambiguity around how to allocate H–1B numbers when the Department receives hundreds of thousands of petitions or registrations requires DHS to establish ''a reasonable H–1B allocation process for such situations.'' Another commenter generally stated that the proposed rule is within the legal framework established by Congress.

Response: DHS agrees with the commenters that it has the statutory authority to implement the beneficiary centric registration selection process, consistent with its authority under section 102 of the HSA, 6 U.S.C. 112, and INA secs. 103(a), 214(a) and 214(c), 8 U.S.C. 1103(a), 1184(a) and 1184(c). These are the same authorities that DHS relied upon to create the registration requirement. *See* 84 FR 888, 894 (Jan. 31, 2019); *see also Liu* v. *Mayorkas,* 588 F.Supp.3d 43, 55 (D.D.C. 2022) (finding that the registration requirement does not violate the INA and is not ultra vires). DHS also agrees that the beneficiary centric registration selection process is a reasonable process for administering the H–1B numerical allocations because it better ensures an equal chance of selection for each unique beneficiary registered for the H–1B cap by a prospective petitioner and systematically reduces the potential for prospective petitioners to have a higher chance of selection by abusing the system and working with others to submit multiple registrations for the same beneficiary.

Comment: An individual commenter stated that it is unclear whether DHS has the statutory authority to implement the proposed beneficiary centric selection process. The commenter remarked that the system would potentially contradict INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), which states that H–1B visas shall be issued ''in the order in which petitions are filed.'' The commenter asserted that the random selection system was justifiable because it was used to determine which petitions were considered to be filed earlier than others, but that the proposed system would not be consistent with this framework. The commenter contended that the proposed system seems to contradict INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), because the commenter believes that the law requires that multiple petitions submitted on behalf of a beneficiary would give them multiple chances to have their petition considered as one of the 65,000 earliest filed.

Response: DHS disagrees with the suggestion that it lacks statutory authority to implement the beneficiary centric registration selection process or that this process would be inconsistent with INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), which states that initial H–1B visas or grants of status shall be issued in the order in which petitions are filed. ''A registration is not a petition.'' *Liu* v. *Mayorkas,* 588 F.Supp.3d 43, 54 (D.D.C. 2022). Registration is merely ''an antecedent procedural step to be eligible to file an H–1B cap[-subject] petition.'' *Id.* at 55. Furthermore, INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), is silent with regard to how to handle simultaneous submissions of H–1B cap-subject petitions. *See Walker Macy LLC* v. *USCIS,* 243 F. Supp. 3d 1156, 1167 (D. Or. 2017). Contrary to the commenter's assertion, the INA does not require USCIS to provide multiple chances for selection for beneficiaries of multiple H–1B cap-subject petitions. Rather, consistent with INA sec. 214(g)(7), 8 U.S.C. 1184(g)(7) (''Where multiple petitions are approved for 1 alien, that alien shall be counted only once''), if multiple employers properly file H–1B cap-subject petitions for a beneficiary selected during the beneficiary centric registration selection process, and if multiple H–1B cap-subject petitions are approved for that beneficiary, the beneficiary will only be counted once

toward the numerical allocations.[6] DHS, therefore, believes that the beneficiary centric registration selection process, similar to the registration-based selection process, is not inconsistent with INA sec. 214(g)(3), 8 U.S.C. 1184(g)(3), and is a permissible exercise of DHS's authority under section 102 of the HSA, 6 U.S.C. 112, and INA secs. 103(a), 214(a) and 214(c), 8 U.S.C. 1103(a), 1184(a) and 1184(c).

Comment: A comment from multiple members of Congress stated that, while it is legal for beneficiaries to have multiple employers submit registrations on their behalf, the current registration system is ''unfair to [beneficiaries] and scrupulous employers, detrimental to the H–1B system, and inconsistent with statutory intent, as individuals with multiple selections may be counted as multiple cap slots.'' These commenters strongly recommended that DHS implement the beneficiary centric system in time for the FY 2025 registration period.

Response: DHS agrees that the beneficiary centric selection approach will improve the fairness and integrity of the H–1B registration process and reduce the possibility for abuse. However, DHS disagrees with the commenters' suggestion that the current registration system is inconsistent with the statute or congressional intent.[7] As stated in previous responses above, DHS has the statutory authority to implement the beneficiary centric registration selection process, consistent with its authority under section 112 of the HSA, 6 U.S.C. 112, and INA secs. 103(a), 214(a) and 214(c), 8 U.S.C. 1103(a), 1184(a) and 1184(c). DHS also agrees that implementing these improvements as soon as possible, and in time for the FY 2025 cap season, will be advantageous to the regulated public and DHS.

2. Background and Data on the Current Registration System

Comment: While citing research published in Forbes on May 1, 2023,[8] a couple of commenters offered general background on selection in the H–1B registration process, stating that the chances of selection have decreased from FY 2021 to FY 2024. A commenter expressed support for the rule, while inaccurately stating that there were ''7.81 million registrations received during the 2024 fiscal year.'' Another commenter conveyed support for the proposed rule by referencing the unprecedented number of registrations received during FY 2024. While referencing the increase in registrations for beneficiaries with multiple registrations, a joint submission expressed a vision of the H–1B registration system in which employers with genuine job opportunities are not disadvantaged by those who manipulate the registration process. Citing the increase in the number of ''applications'' within the past 3 years, a commenter stated that this increase was because of businesses sponsoring multiple applications for the same person.

Response: In FY 2024, there were many more registrations than in previous years. As USCIS stated on its ''H–1B Electronic Registration Process'' website, there were 780,884 total registrations received during the registration period for the FY 2024 H–1B cap.[9] This was a significant increase over prior years. USCIS also stated on its website that, generally, there was an increase in the number of registrations submitted, the number of registrations submitted on behalf of beneficiaries with multiple registrations, and the number of registrations submitted on behalf of unique beneficiaries with only one registration.[10] USCIS further noted on its website that the large number of eligible registrations for beneficiaries with multiple eligible registrations had raised serious concerns that some may have tried to gain an unfair advantage by working together to submit multiple registrations on behalf of the same beneficiary.[11] As DHS noted in the proposed rule, beneficiaries who have multiple registrations submitted on their behalf have a significantly higher chance of selection, while an individual's chance of selection with a single registration is greatly reduced, as the number of beneficiaries with multiple registrations increases under the current system, increasing the number of registrations overall. Through this rule, DHS intends to remedy this situation by implementing the beneficiary centric selection process, where each beneficiary is expected to have the same chance of selection, regardless of the number of registrations submitted on their behalf.

Comment: Referencing Tables 3 and 4 of the NPRM, a commenter remarked that this data was evidence of an increasing trend that undermined the registration system's fairness and efficiency. The commenter added that attention and action are needed to maintain the integrity of the registration system. Another commenter said that the information presented in Tables 2, 3, and 4 of the NPRM shows instances where individuals exploit the current registration system to enhance their chances of selection, thus diminishing the chance of selection for those with only one registration.

Response: DHS agrees that tables 2, 3, and 4 in the NPRM show a concerning trend. As noted in the proposed rule, the data show that multiple registrations on behalf of the same individual are increasing, and this trend negatively affects the integrity of the registration system and selection process.

C. Beneficiary Centric Selection

1. General Support

Comment: Several commenters expressed broad support for the changes to the registration system and implementation of a beneficiary centric selection process without providing additional rationale. Several other commenters expressed support for a system where individuals would only have one chance in the lottery and noted that the proposed measures would reduce multiple ''entries'' without providing additional rationale.

Response: The commenters' reference to multiple ''entries'' is not entirely clear. DHS notes, however, that this rule

[6] *See Liu* v. *Mayorkas,* 588 F.Supp.3d 43, 55 (D.D.C. 2022) (''Consider also that if an alien could have only one employer file a registration on his behalf, that would conflict with § 1184(g)(7). Such a rule would effectively bar any scenario where an alien could have more than one petition approved for him. Section 1184(g)(7) would become meaningless. That is why the Registration Rule allows for multiple registrations. And it adheres to the INA, because 'one alien, one registration' is not in the statutory language.'').

[7] The U.S. District Court for the District of Columbia found that the current registration process is not inconsistent with the INA and is therefore not ultra vires. *See Liu* v. *Mayorkas,* 588 F.Supp.3d 43, 55 (D.D.C. 2022) (''The Rule does not allow more than 65,000 visas (85,000 with the exempt visas included), so it complies with sec. 1184(g)(1). The Applicants do not argue that the Rule allows USCIS to issue visas in any order other than the order in which it receives petitions. Nor could they, because all the Registration Rule does is require prospective employers to file a registration as a first step in the process. A registration is not a petition. The Registration Rule is simply an antecedent procedural step to be eligible to file an H–1B cap petition. So the Rule does not violate sec. 1184(g)(3). And the Rule does not violate sec. 1184(g)(7) because it makes no provision for USCIS to count an alien more than once against the H–1B cap. . . . Because the INA is clear, the Court need not move to *Chevron* step two. And because the Registration Rule does not violate the INA, it is not ultra vires.'') (citations omitted).

[8] Anderson, Stuart, ''Immigration Service Likely to Change H–1B Visa Lottery,'' Forbes (May 1, 2023), *https://www.forbes.com/sites/stuartanderson/2023/05/01/immigration-service-likely-to-change-h-1b-visa-lottery/?sh=5253047d2868.*

[9] USCIS, ''H–1B Electronic Registration Process,'' *https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations-and-fashion-models/h-1b-electronic-registration-process* (last updated July 31, 2023).

[10] *Id.*

[11] *Id.*

does not prohibit multiple registrations for the same beneficiary and will not necessarily reduce the number of registrations for the same beneficiary. The rule is intended to reduce the incentives for submitting multiple non-meritorious registrations on behalf of the same beneficiary. Changing how USCIS conducts the selection process to select by unique beneficiaries instead of registrations will significantly reduce or eliminate the advantage of submitting multiple registrations for the same beneficiary solely to increase the chances of selection and should give all beneficiaries an equal chance at selection.

Comment: Many commenters expressed support for the proposed beneficiary centric selection process on the basis that the revisions are needed or overdue, and some said that making the selection process fair should be a high priority.

Response: DHS agrees that revisions to the current selection process are needed to better ensure that the registration system continues to serve its purpose of efficiently and fairly administering the annual H–1B numerical allocations. DHS believes that a beneficiary centric selection process will likely provide each beneficiary with the same chance for selection without regard to the number of registrations submitted for each beneficiary and will structurally limit the potential for bad actors to game the system because working with others to submit multiple registrations for the same beneficiary will not increase their chance of selection under the beneficiary centric selection process. The final rule also provides that if USCIS determines that registrations were submitted for the same beneficiary by the same or different registrants, but using different identifying information, USCIS may find those registrations invalid and deny or revoke the approval of any H–1B petition filed based on those registrations. DHS believes that these changes are likely to provide an equal chance of selection for each beneficiary and significantly limit the potential for abuse of the registration process.

Comment: Numerous commenters expressed support for the proposed beneficiary centric selection process on the basis that it would have positive impacts on the H–1B program overall, including increasing fairness. These commenters reason that:

- The proposed rule would enhance the fairness and integrity of the selection process overall and one individual should have one entry to the selection process, as it is unfair for individuals to have more than one chance;
- Providing all prospective beneficiaries with an equal opportunity in the selection system would promote social justice and ethical behaviors;
- Concerns with the current uncertainties in the selection process would be alleviated with the changes, which would enhance transparency and predictability in the selection process and help achieve the H–1B program's original objectives;
- The current process harms workers, such as graduates who submit a single entry due to dedication to their prospective employer; and
- Questions on the validity and efficiency of the U.S. immigration system were addressed and that the changes would help restore trust in the system.

Response: DHS agrees with these commenters that the beneficiary centric selection process will likely increase fairness in the selection process, as well as enhance the integrity of the selection process overall. DHS anticipates that this change will also enhance transparency and predictability in the selection process by structurally limiting the potential for bad actors to game the system. As noted in the NPRM, DHS is aware that, under the registration-based selection process, an individual's chance of selection with a single registration is lower compared to beneficiaries who have multiple registrations submitted on their behalf and is optimistic that the new beneficiary centric selection system will increase fairness and help restore trust in the system.

Comment: Many commenters supported the proposed registration selection process because it would reduce abuse in the system, reasoning that:

- The current system is abused by some companies and individuals, who submit multiple registrations on potential beneficiaries' behalf, unfairly strengthening their own chances, and reducing the chances of other applicants being selected;
- The revised process would curb fraud, misuse, and manipulation in the registration system, with some commenters additionally providing anecdotal accounts of fraud and abuse under the current system; and
- Changes to the current system are needed to address loopholes that allow fraudulent submissions.

Response: DHS agrees that changes to the current system are needed to address misuse of the system and better ensure that the registration system continues to serve its purpose of efficiently and fairly administering the annual H–1B numerical allocations. DHS agrees that some registrants have attempted to abuse the registration process to improve the chance of selection for some beneficiaries while reducing the chances of selection of other potential beneficiaries. The beneficiary centric selection process in this final rule is designed to provide each beneficiary with the same chance for selection without regard to the number of registrations submitted for each beneficiary and will structurally limit the potential for bad actors to game the system because working with others to submit multiple registrations for the same beneficiary will not increase their chance of selection under the beneficiary centric selection process. Under the beneficiary centric process, USCIS will select by each unique beneficiary such that each beneficiary should have the same chance for selection, whether they are the beneficiary of one registration or one hundred registrations. DHS has a strong interest in ensuring that the annual numerical allocations are going to petitioners that truly intend to employ H–1B workers and anticipates that the revised selection process will reduce fraud, misuse, and manipulation in the registration system.

Comment: Multiple commenters expressed support for the changes based on programmatic improvements with respect to reducing administrative burdens and the number of times the lottery must be run. These commenters remarked that the proposed changes would enhance efficiency and reduce the probability of needing to perform additional selection rounds. Commenters noted that duplicate registrations under the current selection method wasted limited cap H–1B numbers and created a time and cost burden for USCIS since the agency had to run the lottery multiple times. A few commenters also noted that running the lottery multiple times could negatively affect potential beneficiaries who cannot stay in the United States to wait for additional lottery rounds to be run.

A couple of commenters discussed how losses for U.S. employers under the current system result in additional costs, administrative burdens, and instability. Some commenters noted that the proposed rule would reduce the administrative burden for companies aiming to register potential beneficiaries under the current registration system, streamlining the process for both registrants and government agencies. Additionally, a couple of commenters wrote that the proposed selection process would reduce administrative

and financial burdens on U.S. companies and employers.

Response: DHS appreciates commenters for their feedback supporting the change to a beneficiary centric selection process and their assertions that this change will reduce administrative burdens for companies and enhance efficiency. Additionally, DHS appreciates the comments that some companies face hiring instability under the current registration-based selection process because the chance of selection is low; and, they may have been required to wait through multiple selection rounds to find out if their registration for a beneficiary had been selected. With respect to agency administrative burdens, even under the beneficiary centric selection process, it is possible that USCIS may be required to conduct more than one round of selections depending on how many petitions are filed based on valid registration selections following the initial or subsequent selection round. Therefore, DHS cannot forecast with certainty a reduction in administrative burdens resulting from fewer selection rounds. However, the beneficiary centric selection process may reduce the likelihood that USCIS will need to run the selection process more than once in a fiscal year and may achieve the multiple benefits discussed by the commenters. DHS also acknowledges the comments that running multiple selection rounds can negatively affect beneficiaries who are already in the United States and may not be able to stay through multiple selection rounds, and notes that the beneficiary centric registration process may help potential beneficiaries in this manner as well.

Comment: Numerous commenters discussed the negative impact of the current selection process on fairness, stating that prospective beneficiaries with one registration or those who comply with H–1B policies struggle to be selected for an H–1B number due to ongoing abuse and decreasing selection rates. Some commenters noted that those who comply with registration requirements are unfairly disadvantaged or effectively penalized for their decision not to engage in fraud, which results in inverse selection bias and moral hazard and causes stress for beneficiaries. Many commenters expressed support for the proposed beneficiary centric selection and said that the proposed selection process would promote equity and fairness among prospective H–1B beneficiaries, and provide prospective beneficiaries with an equal opportunity for selection. Several commenters stated that the proposed process would improve opportunities for selection for individuals with one offer or registration and discourage ''unnecessary competition'' among beneficiaries.

Response: DHS agrees with these commenters that the chances of selection in the current registration-based cap selection process are lower for beneficiaries with only one job offer and that this may be due, in part, to some registrants trying to game the system by working with others to submit multiple registrations for a single beneficiary. DHS agrees with these commenters that the new beneficiary centric selection process will increase fairness for registrants and beneficiaries and anticipates that changing the selection process will discourage organizations and beneficiaries from trying to game the system.

Comment: A commenter stated that ethical and integrity-driven individuals are naturally disinclined to engage in fraudulent activities. The commenter indicated that the beneficiary centric selection process would, therefore, not only combat fraud but also foster an environment that prioritizes ethics and honesty. The commenter stated that preventing H–1B program abuse will safeguard the country's values and bolster the nation's economic and national security, among other benefits.

Response: DHS appreciates the commenter's feedback on the various benefits of the beneficiary centric selection process and agrees that the new beneficiary centric selection process will increase fairness for all prospective beneficiaries.

Comment: Some commenters expressed support for the proposed registration selection process on the basis of improved flexibility, greater autonomy, and more agency for beneficiaries. A few commenters wrote that the proposed process would empower candidates to select the employer for whom they ultimately work. Additionally, a commenter said that beneficiary centric selection would provide beneficiaries with better bargaining power, ensuring that employers do not undercut wages. Another commenter wrote that the proposed rule would allow beneficiaries to negotiate with companies for higher salaries upon selection, which the commenter said would create an ''imbalance in salaries.''

Response: DHS generally agrees with these commenters. As noted in the NPRM, the new beneficiary centric selection process may benefit beneficiaries by giving them greater autonomy to choose the employer for whom they ultimately work without decreasing their chances of selection. 88 FR 72870, 72899 (Oct. 23, 2023). If multiple unrelated companies submit registrations for a beneficiary and the beneficiary is selected, then the beneficiary could have flexibility to determine which company or companies could submit an H–1B petition for the beneficiary, because all of the companies that submitted a registration for that unique beneficiary would be notified that their registration was selected and they are eligible to file a petition on behalf of that beneficiary. 88 FR 72870, 72899 (Oct. 23, 2023). While DHS cannot predict whether or how the beneficiary centric system would affect salaries, H–1B beneficiaries already possess and may exercise autonomy to change to another H–1B employer offering a higher salary or preferred work conditions.[12]

Comment: Commenters discussed benefits and impacts on specific populations of prospective beneficiaries. For example, some commenters wrote that the proposed changes would ensure fairer opportunities for international students, particularly those on F–1 student visas. In addition, a commenter said that the proposed rule would make the process fairer for highly skilled workers, as the current system favors low-skilled workers who ''take the majority of the quota,'' through multiple registrations.

Response: DHS's goal is to set a level playing field for all potential beneficiaries so that all beneficiaries may have a fair chance of selection through the revised beneficiary centric selection process.

Comment: Several commenters expressed support for the proposed selection process, opining that it would benefit U.S. employers and companies. Multiple commenters, including a company, discussed challenges for employers to meet workforce needs under the current registration selection system, including: the inability to retain talent due to falling selection rates, the loss of talent as a result of prospective employees leaving their U.S. employers or the United States, hesitation among employers to hire foreign workers, disadvantages for small to medium enterprises that do not have the means to outsource their workforce, and hampering company efforts to expand, such as the inability to expand semiconductor design and manufacturing efforts.

Many commenters remarked on how the proposed selection process would benefit employers or remediate the above challenges, stating that the

[12] *See* INA section 214(n), 8 U.S.C. 1184(n).

revisions would: generally align with or protect the interests of U.S. companies; allow U.S. companies to attract, increase, or retain foreign talent and a skilled workforce; promise a targeted or more precise allocation of visas to cater to the needs of U.S. employers; boost the confidence of U.S. employers to hire international workers; decrease disruption in the hiring and talent management process; increase the productivity and competitiveness of U.S. businesses; and benefit underserved businesses.

Response: DHS appreciates the feedback that the beneficiary centric selection process will improve employers' ability to attract and retain foreign talent and lessen their administrative burden in managing a competitive workforce. DHS anticipates that this approach will create a more level playing field so that all beneficiaries may have a fair chance of selection. While DHS cannot gauge all of the impacts of this selection process, DHS appreciates the commenters' assessments that it may improve employee retention, increase productivity, and boost confidence in hiring international workers.

Comment: Numerous commenters endorsed the beneficiary centric selection process based on potential outcomes for the U.S. economy overall. Many of these commenters expressed concern with the current selection process and its associated outcomes on the U.S. economy and workforce, including: preventing the United States from retaining skilled foreign workers; the loss of global competitiveness, particularly in the technology sector; stifled innovation and growth; job market distortion and unpredictable workforce availability, as a result of individuals accepting more offers than they can take; discrimination against industries that restrict the number of offers one can accept; harms to the education industry and universities through the loss of international students; and increased reliance on outsourcing, which negatively impacts tax revenue and the local job market.

Commenters stated that the proposed selection process would positively impact the U.S. economy by: encouraging innovation and economic growth and fostering technological advancements, research breakthroughs, and entrepreneurship, which stimulate economic growth and job opportunities; bolstering the United States' competitive position in the global economy; benefitting U.S. and international workers who contribute to the U.S. economy; minimizing labor shortages; ensuring that the United States can attract highly skilled foreign professionals; ensuring a more stable and reliable immigration system that benefits the strength and resilience of the U.S. economy; and promoting diversity in the U.S. workforce.

Multiple commenters endorsed the proposed selection process on the basis that it would give prospective beneficiaries the opportunity to remain in the United States and contribute to the U.S. economy, stating that:

- Difficulties with H–1B selection have caused prospective workers to leave the United States, with some commenters providing anecdotal remarks to support this view;
- By rewarding ''volume over veracity,'' the current system diminishes the ability of prospective beneficiaries to apply their skills in the U.S. job market; and
- Current abuse within the selection system deters companies from extending offers to international workers.

In light of the above concerns, several commenters said that the proposed revisions to the selection process would instead encourage international talent to work in the United States and benefit foreign professionals who already contribute—or aspire to contribute—to the U.S. economy.

Response: DHS appreciates these commenters' assessments that the new selection process will positively impact the U.S. economy and that the U.S. economy may benefit from foreign talent through a revised H–1B selection process. DHS anticipates that the beneficiary centric selection process will benefit U.S. companies and prospective beneficiaries who will contribute to the U.S. economy by creating a fairer selection process.

2. General Opposition

Comment: An individual commenter opposed the beneficiary centric process on the grounds that it will decrease the chances of highly talented or highly qualified beneficiaries to be selected. The commenter explained that an extraordinary candidate should have a higher chance of selection compared to a less qualified candidate, and that it is unfair to give these different candidates the same chance of selection. The commenter stated that USCIS should act against fraudulent companies rather than decrease the chance of selection for highly talented or qualified individuals with multiple job offers.

Response: Under the current registration-based selection process, beneficiaries with multiple legitimate job offers and registrations are potentially being crowded out by multiple registrations for beneficiaries with frivolous job offers. Therefore, an individual's chance of selection based on one or two registrations is much less than the chance of selection based on, for example, 80 plus registrations as was seen in FY 2023. The new beneficiary centric selection process is designed to provide all individuals, even those with legitimate multiple registrations, with an equal chance of selection as opposed to the diminished chances under the current process. DHS recognizes that the change to the beneficiary centric selection process could potentially decrease the chance of selection for some beneficiaries with multiple job offers. It, however, is not clear from the comment whether or how the population of beneficiaries with multiple job offers overlaps with the population of ''extraordinary candidates,'' as the selection process does not take into account the beneficiary's qualifications. Even if there is such an overlap, DHS believes the benefits of leveling the playing field for all beneficiaries outweigh the possible negative consequences to some individuals. Moreover, extraordinary or highly qualified candidates may have options outside of cap-subject H–1B employment and could obtain employment in the United States through alternate paths, such as employment with a cap-exempt H–1B petitioner or an O–1 nonimmigrant visa. Additionally, DHS appreciates other commenters' feedback that certain industries or companies have ethics rules that prevent individuals from accepting job offers from more than one company at a time, and by extension, prevent them from having multiple H–1B registrations submitted on their behalf. As these commenters have indicated, the number of registrations an individual has is not always an accurate proxy of their talent or desirability as a candidate for employment.

Finally, because the H–1B registration process is merely an antecedent procedural step before the H–1B petition may be properly filed and adjudicated, and is not itself an adjudication, DHS does not believe that it could implement a selection process based on a relative comparison of various beneficiaries' qualifications and still retain the original aim for creating the registration process in the first place—an efficient process based on minimum information necessary to administer the annual statutory H–1B numerical allocations.

Comment: A commenter stated it opposes the rule because, as an organization, it relies on students who

are not selected in the H–1B lottery for its profits.

Response: DHS disagrees with this comment. The purpose of the registration system is to provide for the fair and orderly administration of the annual H–1B numerical allocations, not to provide profits for certain companies. DHS strongly supports fairness in the selection process and believes that the beneficiary centric selection process in this final rule will provide each beneficiary with the same chance for selection.

3. Identifying Information and Passport Requirement

Comment: Several commenters stated that the use of passport numbers as identifying information would help mitigate fraud and promote fairness in the registration system by providing everyone with an equal chance in the beneficiary centric selection process. In addition to promoting fairness, a commenter remarked that the use of a unique passport number adds an additional layer of transparency and traceability to the selection process, which minimizes the potential for manipulation or bias. A commenter expressed support for the requirement, reasoning that citizens from countries where visas are mandatory to enter the United States already submit passport information.

Response: DHS agrees with these commenters that the requirement of a passport number at the time of registration under the beneficiary centric selection process will help mitigate fraud and abuse of the registration selection process. In response to other public comments discussed in this preamble, DHS has decided to modify this proposed requirement in this final rule by expanding the types of acceptable documents so that the registration must include either the beneficiary's valid passport information or valid travel document information. DHS is making this modification in order to narrowly accommodate stateless individuals, refugees, and other individuals who are unable to obtain valid passports. DHS believes that this modified requirement of a passport or travel document will still help to mitigate fraud by allowing USCIS to accurately identify each unique beneficiary, which is integral to the integrity of the beneficiary centric selection process and the goal of creating a fairer registration system.

Comment: Some commenters stated that the proposed rule does not indicate how USCIS will review petitions that have explainable discrepancies. The commenters suggested that DHS clarify in the regulations that a petition with explainable discrepancies will be receipted by USCIS and that the petitioner will be provided an opportunity to explain the discrepancy.

Response: As proposed, new 8 CFR 214.2(h)(8)(iii)(D)(*1*) provides that USCIS may deny an H–1B petition or revoke an approved H–1B petition if there is a change in the beneficiary's identifying information from registration to petition filing. The regulatory text does not state that USCIS will reject an H–1B petition if there is a change in the beneficiary's identifying information. As further explained in the NPRM, USCIS will typically afford the petitioner the opportunity to respond when identifying information provided on the registration does not match the information provided on the petition, and petitioners would need to be prepared to explain and document the reason for any change in identifying information. 88 FR 72870, 72898 (Oct. 23, 2023). DHS believes that the regulatory text, combined with the preamble explanation in the NPRM and this explanation, is sufficiently clear to explain that USCIS will receive these petitions and that the petitioner will have the opportunity to explain the discrepancies prior to denial or revocation.

Comment: Several commenters expressed appreciation for USCIS' effort to reduce fraud in the H–1B selection process but at the same time expressed concern over potential impacts on stateless individuals, refugees, and other persons who are unable to obtain valid passports. For instance, an individual commenter stated that USCIS should also accept registrations for beneficiaries who are refugees and cannot obtain a passport from their country of origin. The commenter suggested that USCIS use other travel documents from countries of refugees instead of only passports. The commenter added that these documents contain identification numbers similar to passport numbers, and that existing Department of State practices permit visas to be issued on these documents. An individual commenter expressed their belief that it is unfair to bar stateless individuals from obtaining a cap-subject H–1B visa, which would severely restrict the ability of U.S. employers to hire these individuals. A joint comment from two advocacy groups commended USCIS' ''demonstrated concern for stateless individuals'' and stated that USCIS should allow individuals to provide a unique identifier other than a passport, accompanied by an explanation of why they cannot obtain a valid passport. Another commenter expressed concern that the requirement to submit valid passport information would prevent employers from submitting registrations for stateless individuals, those unable to extend or renew passports, refugees, people who have fled their countries, and individuals with lost or expired passports. The commenter suggested that the registration process should have an option for registrants to attest that beneficiaries are stateless, with additional data requirements verifying identity for this group such as asking for an A-number or an employment authorization document (EAD) card number that could serve as an acceptable identification substitute for the passport number. A different commenter suggested USCIS accept ''alternative identity documentation, provided by a national, State, or local government or an international organization,'' out of concern for stateless individuals, refugees, other individuals who were forced to flee their country without passports, and other individuals who are unable to obtain valid passports. Another commenter similarly suggested that DHS accept alternative documents ''including other federal or State issued identification documents that provide similar security integrity safeguards'' as passports. Other commenters suggested adding a disclaimer on the registration that falsely claiming to be a stateless individual will result in the denial of a subsequently filed H–1B cap petition and revocation of the registration selection notice. A comment from multiple members of Congress recommended that DHS ''create an exception to the passport requirement for stateless individuals and those who are unable to obtain a valid passport due to extraordinary circumstances outside their control.''

Response: In light of these comments—and consistent with the Administration's dedication to promoting access for refugees and stateless individuals—DHS is allowing either the beneficiary's valid passport information or valid travel document information to be submitted for H–1B registration purposes. *See* new 8 CFR 214.2(h)(8)(iii)(A)(*4*)(*ii*) and 214.2(h)(8)(iii)(D)(*1*). As stated above, this modification is intended to narrowly accommodate stateless individuals, refugees, and other individuals who are unable to obtain valid passports. DHS believes that it is important to accommodate especially vulnerable populations, such as stateless individuals and refugees. At the same time, this narrow accommodation is not expected to

significantly increase the risk that a beneficiary would be registered under more than one identity document, as a valid travel document that the beneficiary intends to use to enter the United States is inherently limited to a single document.

DHS declines to allow additional types of identifying documentation for H–1B registration purposes. While a narrow accommodation to the passport requirement is not expected to significantly increase the risk that a beneficiary would be registered under more than one identity document, DHS believes that allowing additional identifying documentation would make the registration system more susceptible to abuse. Adding more types of acceptable documentation will heighten the likelihood that beneficiaries would have more than one document that could be used for registration to game the system and give them more than one chance in the selection. For example, a beneficiary could have multiple EAD card numbers or have both an EAD card number and a passport number. However, DHS does not believe that an individual would likely have both a valid passport and a valid travel document that they intend to use to enter the United States in H–1B status; it is unclear what legitimate reason an individual would have to use both a valid passport and another valid travel document when seeking to enter the United States in H–1B status. Further, ''alternative identity documentation provided by a national, State, or local government or an international organization'' or ''other federal or state issued identification documents'' could encompass a broad range of documents of varying credibility which increases the potential for abuse. For instance, an ''alternative identity document'' could include a state or provincial identity card, driver's license, cedula, matricula consular, or other civil identity or vital statistics document which is not considered a travel document and is not valid for entry to or departure from the United States by air.[13] It is not clear what advantage would be gained by expanding the universe of acceptable documents to an EAD card or another alternative identity document that cannot be used to enter the United States in H–1B status, in line with the purpose of submitting a registration for the prospective beneficiary in the first place, compared to the increased risk for fraud that broadening the universe of acceptable documents would pose.

DHS also declines to add a new attestation on the registration that falsely claiming to be a stateless individual will result in the denial or revocation of the H–1B petition, or finding the registration invalid. As stated above, DHS has modified the passport requirement to also allow for a valid travel document. While this modification is intended to narrowly accommodate stateless individuals, refugees, and others who are unable to obtain valid passports, it is not limited to such individuals; thus, it is not necessary to add a new attestation regarding false claims of statelessness or other claims regarding why an individual does not have a valid passport. In addition, the registration tool continues to ask for the beneficiary's country of citizenship and provides an option for the registrant to list the beneficiary as ''stateless.'' The registration tool also continues to require the registrant to certify, under penalty of perjury, that they have reviewed the registration(s) and that all of the information contained in the submission is complete, true, and correct.

Comment: A commenter stated that, while passport information is helpful, ''there are legitimate reasons why a registrant may be unable to provide valid passport information, and excluding those registrants is antithetical to ensuring they can petition for the best and brightest.'' The commenter noted that it is reasonable to assume that some individuals may not have valid passports at the time of registration but would be able to obtain them by the time of filing a petition, and suggested DHS retain the option to allow beneficiaries to register if they certify that they do not have a valid passport.

Response: As noted above, DHS will retain the passport requirement in the final rule but has modified the proposed passport requirement to also allow for a valid travel document. Requiring valid passport or travel document information, combined with the other collected biographical information, will allow USCIS to identify unique individuals more reliably, increasing the likelihood that each individual would have the same opportunity to be selected, if random selection were required. While DHS recognizes that some individuals may not possess a valid passport or travel document, DHS has a strong interest in requiring passport or travel document information for each beneficiary, regardless of nationality, to better identify unique beneficiaries and enhance the integrity of the H–1B registration system. Further, and consistent with what DHS stated in the NPRM, DHS believes that requiring passport or travel document information is reasonable because each registration should represent a legitimate job offer. In the absence of a valid passport or travel document, it is not clear how most beneficiaries could enter the United States in H–1B status pursuant to that job offer. Therefore, this rule will only accelerate the time by which the beneficiary needs to obtain a passport or travel document if the beneficiary does not already have one of those documents. *See* 88 FR 72870, 72898 (Oct. 23, 2023).

Comment: Several commenters expressed concerns with fraud related to the passport requirement. These commenters indicated that a passport number alone is insufficient to identify a unique beneficiary because individuals are able to obtain multiple passports or fraudulent passports. For example, a commenter said that people with dual citizenship or citizenship in multiple countries could potentially exploit the registration system by filing with different passport numbers and country of issuance. One commenter mentioned the potential exploitation of the system from individuals using multiple identities or passports from different countries, while a couple of other commenters expressed concern that individuals might abuse or circumvent the proposed passport requirement and discussed the importance of using additional identifiers to avoid potential fraud.

Several commenters provided alternatives related to identifying information, suggesting that USCIS:

- Link a registration or the definition of ''unique'' to an individual's Social Security number (SSN) or Individual Taxpayer Identification Number (ITIN);
- Require a history of passports;
- Include a declaration of authenticity or an affirmation of truth;
- Require additional information, including the name, date of birth, place of birth, and similar information in addition to passport information;
- Verify passport information provided on registrations and petitions are correct and legitimate;
- Require a photograph (and use face recognition technology) at registration, or require both a photo and passport

[13] CBP, ''Carrier Information Guide: United States Document Requirements for Travel,'' *https://www.cbp.gov/sites/default/files/assets/documents/2023-Nov/Carrier%20Information%20Guide%20ENGLISH.pdf* (stating that ''National identity cards, cedulas, matriculas consular, certificates of citizenship, certificates of naturalization and other civil identity or vital statistics documents are NOT considered travel documents and are NOT valid for departure from the U.S. by air,'' and listing a driver's license, birth certificate, matricula consular, cedula, and national identification card as among the examples of documents that are ''not acceptable for entry to or departure from the United States.'').

number to be submitted on the visa petition and with any lottery registration application to ensure the beneficiary is the same person at every step;

- Use an alternative process where a prospective beneficiary submits a registration with their personal information (including passport information) to USCIS, and USCIS will send that prospective beneficiary a confirmation PDF containing a unique confirmation number employers can then use to identify and register the beneficiary; and
- Require prospective beneficiaries to ''provide biometric information during the application process.''

Response: DHS has considered the concern of potential exploitation through using fraudulent passports or multiple passports. DHS believes that using a passport number as a unique identifier is a reasonable approach that appropriately balances the interests of integrity in the selection process with access to the registration system. DHS also believes its expansion to allow for a valid travel document in lieu of a valid passport does not significantly increase the risk of exploitation through using fraudulent or multiple travel documents, particularly since a valid travel document that the beneficiary intends to use to enter the United States is inherently limited in scope. Further, the regulations clearly state that a beneficiary may only be registered under one passport or travel document. *See* new 8 CFR 214.2(h)(8)(iii)(A)(*4*).

The final rule also contains other safeguards that are sufficient to address potential exploitation. The regulations at new 8 CFR 214.2(h)(8)(iii)(A)(*2*), make clear that a beneficiary having multiple registrations filed on their behalf using different identifying information is grounds for finding the registrations invalid and denying, or revoking the approval of, any H–1B petition filed on their behalf. Thus, if USCIS determines that registrations were submitted for the same beneficiary but using different passport information, USCIS would have the authority to invalidate such registrations and deny or revoke the approval of any H–1B petition filed based on those registrations under new 8 CFR 214.2(h)(8)(iii)(A)(*2*). USCIS may do so even if the beneficiary had more than one valid passport or travel document, such as a beneficiary with dual citizenship who has passports issued by different countries.[14]

USCIS will also continue to require information on a beneficiary's legal name, date of birth, and country of birth as part of the registration process. USCIS will use this information to analyze registration information and identify instances where beneficiaries are registered with different identifying information. When USCIS identifies such instances, any H–1B petition filed for that beneficiary may be subject to denial or revocation.

With respect to comments that suggested USCIS use a Social Security number or individual taxpayer identification number as a unique identifier, DHS believes requiring a Social Security number or individual taxpayer identification number would not be feasible as individuals who have never held H–1B status or another nonimmigrant status or employment authorization in the United States likely would not have such numbers. In regard to the suggestion to collect biometrics, including photos, for beneficiaries prior to the registration process, DHS notes that collecting biometrics for all beneficiaries prior to registration would be operationally infeasible for USCIS and would add additional burdens for beneficiaries, especially those overseas. In regard to the suggestion to collect a history of passports, DHS believes this would be overly burdensome for USCIS, registrants, and beneficiaries. DHS will collect sufficient information to enable USCIS to identify the beneficiary of the registration, check for duplicate registrations submitted by the same prospective petitioner, and match selected registrations with subsequently filed H–1B petitions, without overly burdening the employer or collecting unnecessary information, in compliance with the Paperwork Reduction Act (PRA). Requiring a valid passport or valid travel document strikes the balance between protecting the integrity of the registration system and maintaining accessibility to the registration system and the H–1B program.

With respect to the suggestion that USCIS include an affirmation of truth on the registration, in completing the H–1B registration, the registrant must already certify, under penalty of perjury, that the information contained in the registration is complete, true and correct. The registrant must also certify that the registration reflects a legitimate job offer, and that the registrant intends to file an H–1B petition on behalf of the individual named in the registration. DHS believes the existing attestations are sufficient.

DHS also considered the suggestion that USCIS use an alternative process where a prospective beneficiary receives a unique confirmation number from USCIS after submitting their passport number, which the beneficiary would then give to potential employers to enter in the registration system. This alternative process, however, would not be any more effective than identifying a prospective beneficiary by their valid passport or travel document information as provided by a prospective petitioner or its representative because DHS would continue to rely on the beneficiary to provide accurate information to both DHS and the prospective petitioner or its representative. This two-step process would add additional time to the overall registration period with no explanation provided of how it would enhance identity verification more than the proposed beneficiary centric process.

4. Implementation and Effective Date

Comment: Numerous commenters requested that USCIS implement the rule for the FY 2025 cap season (the H–1B registration period and related selection process beginning in March 2024). Many commenters requested the proposed rule be implemented as soon as possible. A couple of commenters similarly requested swift implementation of the proposed rule with no specified timeframe, while a few commenters remarked that they hope the proposed rule could take effect ''right now''. One commenter stated it is likely that multiple registrations will ''skyrocket'' this upcoming H–1B cap season without immediate implementation of the beneficiary centric provision. Additionally, a commenter asked DHS to consider whether this portion of the NPRM should proceed separately and be promulgated as an interim final rule as soon as possible in order to ensure that it is in effect in advance of the 2024 cap registration cycle.

Multiple commenters stated that quick implementation of the proposed rule would increase fairness, equity, and integrity in the registration process. A commenter said that the planned implementation for the FY 2025 H–1B cap season demonstrated the government's commitment to improving the immigration system. Another commenter stressed the need for implementation ''before next year's selection process,'' reasoning that potential beneficiaries have time constraints for getting the H–1B visa

[14] *See* ''Modernizing H–1B Requirements, Providing Flexibility in the F–1 Program, and Program Improvements Affecting Other Nonimmigrant Workers,'' 88 FR 72870, 72898 (Oct. 23, 2023) (''Even if a beneficiary had more than one valid passport, such as a beneficiary with dual citizenship, a beneficiary would only be able to be registered under one of those passports.'').

when they work with F–1 OPT or STEM OPT.

Response: DHS agrees with the need for prompt implementation of this rule. This rule will be effective in time for the FY 2025 H–1B cap season (the H–1B registration period and related selection process beginning in March 2024).

Comment: Some commenters encouraged DHS to separate and move forward with the proposed H–1B registration changes for the upcoming cap season, but to refrain from finalizing any of the other provisions until it has sufficiently considered stakeholder feedback. Another commenter requested DHS to consider implementing these changes in phases so that stakeholders will be aware of what is coming.

Response: As stated above, DHS will finalize the proposed H–1B registration changes and other registration-related provisions in time for the FY 2025 H–1B cap season. DHS continues to consider public comments received on the other proposed changes included in the October 23 NPRM and plans to issue a separate final rule to finalize or otherwise address those proposed changes.

5. Other Comments on the Beneficiary Centric Selection Process

Comment: A few commenters requested clarification on the process for registrants after a beneficiary is selected. A commenter asked whether USCIS would adjudicate all petitions filed for a beneficiary or whether the Department would randomly select an employer. Another commenter encouraged DHS to clarify whether it permits all selected registrants to file an H–1B petition or if it will only allow one of the selected registrants to proceed. Additionally, a commenter asked DHS to include a clearly defined systemic mechanism that allows employers to know how to submit the sponsoring petition if a beneficiary has had multiple employers submit a registration on their behalf thereby eliminating the need for employers to solely rely on their beneficiaries to share this information.

Response: Where a selected beneficiary has multiple H–1B petitions that are properly filed on their behalf based on valid registrations, USCIS will adjudicate each petition. DHS did not propose to, nor will it, randomly select an employer whose petition it will adjudicate. As the NPRM states, if a beneficiary were selected, each registrant that submitted a registration on that beneficiary's behalf would be notified by USCIS of selection and would be eligible to file a petition on that beneficiary's behalf.[15] This is not a change from the current registration system, under which more than one registrant can register for the same beneficiary and any selected registrant is eligible to file an H–1B petition on behalf of that beneficiary if the petition is based on a valid registration selection notice. More than one registrant can file a petition on behalf of a single selected beneficiary and USCIS will adjudicate all properly filed petitions. DHS has no role in deciding which registrants ultimately choose to file a petition based on their selected beneficiary. It is expected that registrants will communicate with the selected beneficiary to make informed decisions regarding whether to file an H–1B petition.

Comment: Several commenters noted concerns with allowing multiple registration entries for an individual, and suggested changes to the registration system to prohibit or reject multiple registrations for a single beneficiary. One commenter suggested that only the submission for a beneficiary from the ''most current employer'' should be valid and all others voided. Another commenter specified that DHS should not only eliminate the ability for related entities to submit a single registrant multiple times, but also prevent unrelated registrants from submitting multiple registrations for a beneficiary. Some of these commenters stated generally that multiple registrations should not increase the chance a beneficiary is selected, as submitting multiple entries for one individual is unfair to other individuals. Additionally, a commenter remarked that duplicate entries for beneficiaries by consultancies undermines the fairness of the selection process. Another commenter, expressing support for the proposed registration process, remarked on other negative impacts of current abuse on the H–1B program stating that since H–1B holders can legally work for only one employer at a time, there is no rationale for selecting multiple entries for a potential beneficiary in the lottery system and wasting USCIS resources.

Response: Like the commenters, DHS is concerned with the integrity of the registration system and attempts to circumvent the selection process under the current registration system. As such, the focus of this rule is to ensure that each individual beneficiary has an equal chance of selection and to remove the advantage of submitting multiple registrations for the same beneficiary to increase the chances of selection. However, DHS declines to restrict the registration process to one total registration per beneficiary. DHS acknowledges that there could be legitimate reasons for an individual to have more than one registration submitted on their behalf. Moreover, the beneficiary centric selection process will essentially accomplish the goal these suggestions seek to achieve, which is to ensure that each individual beneficiary has an equal chance of selection and reduce fraud.

Comment: Some commenters expressed the need for DHS to allow registrants to view if multiple registrations have been submitted for a beneficiary. For instance, a commenter generally supported the proposed beneficiary centric system but expressed a need to ''[ensure] fairness for employers who invest in foreign national talent'' by providing employers with visibility into a beneficiary's multiple registrations. The commenter recommended that USCIS include in the selection notification to employers an indication of either: (1) the number of employer registrations; or (2) whether the beneficiary has one or multiple employer registrations. The commenter stated that such information will help employers make more informed decisions when deciding to invest significant resources to file an H–1B petition and will also help reduce any legal consequences that may arise from multiple petitions being approved for the same beneficiary. Other commenters similarly requested USCIS to institute a mechanism that informs a potential employer that a beneficiary has more than one registration. One commenter suggested it would be fair for the U.S. employer to see if the beneficiary has multiple registrations because the H–1B is employer-sponsored.

Response: While DHS agrees that the H–1B process is employer-sponsored, DHS declines to make these suggested changes. It is expected that prospective petitioners will communicate with their selected beneficiaries to make informed decisions regarding whether to file an H–1B petition. DHS also notes that the beneficiary centric selection process does not substantially differ from the current registration-based selection process in this regard and remains an employer-driven process given that registrations and petitions will continue to be submitted by sponsoring

[15] ''Modernizing H–1B Requirements, Providing Flexibility in the F–1 Program, and Program Improvements Affecting Other Nonimmigrant Workers,'' 88 FR 72870, 72898 (Oct. 23, 2023) (''If a beneficiary were selected, each registrant that submitted a registration on that beneficiary's behalf would be notified of selection and would be eligible to file a petition on that beneficiary's behalf. See proposed 8 CFR 214.2(h)(8)(iii)(A)(1) and (4).'').

employers. A beneficiary in the current registration-based selection process may have multiple valid registrations selected that were submitted on their behalf by different companies, and thus have multiple petitions filed on their behalf by different companies based on those valid registration selection notices. Allowing for multiple cap petitions is consistent with INA section 214(g)(7), 8 U.S.C. 1184(g)(7), which states that when multiple cap petitions are filed and approved for a beneficiary, the beneficiary shall only be counted once toward the H–1B numerical allocations. DHS also believes that the commenter's suggestions regarding sharing information about registrations submitted by other prospective petitioners for a selected beneficiary goes beyond the intent of the narrow changes implemented in this final rule, which is to better ensure that each unique beneficiary has the same chance of selection in the H–1B registration selection process. As such, DHS declines to adopt the commenters' suggestions.

Comment: A commenter expressed support for allowing all companies that submitted a registration for a selected beneficiary to file an H–1B petition. The commenter noted possible negative consequences of not limiting the number of H–1B petitions that can be submitted for a selected beneficiary but concluded that allowing all companies that submitted a registration for a selected beneficiary to file an H–1B petition is ''a good solution.'' For example, the commenter noted that requiring a beneficiary to choose only one employer upon which to proceed with H–1B filing will be detrimental to the beneficiary if that sole petition is not approved or if it is approved and the beneficiary loses the job after approval but before the effective date.

Response: DHS appreciates the commenter's feedback and confirms that generally all prospective petitioners that properly submitted a registration for a selected beneficiary will be eligible to file an H–1B petition for the beneficiary named in their registration selection notice during the applicable filing period, provided that they are not related entities without a legitimate business need to file multiple cap petitions.

Comment: Some commenters requested clarity on how multiple H–1B petition approvals would affect a beneficiary's status. A commenter urged DHS to ''clarify and codify that each approved H–1B petition is valid, and that neither the date of filing, the date of adjudication (benefiting those filing with premium processing), or the requested start date (for those chosen in later selections) impact the validity of an approved H–1B petition, and that the beneficiary can commence work under any of the approved petitions even if another petition in the same H–1B filing period is subsequently approved.'' Another commenter asked for clarity regarding possible status issues that could result from the current NPRM, including clarifying that a petition is only ''active'' when the beneficiary begins to work for the petitioner. This commenter stated that such clarification will be particularly important if DHS finalizes its proposal regarding a flexible start date. A different commenter asked for clarification that ''any filed and approved petitions will remain valid until withdrawal by the petitioner'' and noted that multiple petition approvals requesting change of status may cause confusion regarding the beneficiary's status.

Response: The filing of multiple petitions for the same beneficiary has always been a possibility, such as in concurrent employment situations. DHS confirms that an approved H–1B petition may remain valid notwithstanding the subsequent approval of an H–1B petition for the same beneficiary. DHS further confirms that upon approval of a cap-subject petition, including a request for change of status, the starting validity date will be the start date reflected on Form I–797, Notice of Action (Approval Notice), notwithstanding the date of filing, the date of adjudication, or the requested start date on the petition. DHS also confirms that a beneficiary may commence work under any of the approved petitions as long as they remain valid and the beneficiary is in H–1B nonimmigrant status, as is the case under current practice. Given that the regulation states that a petitioner shall immediately notify USCIS of any changes in the terms and conditions of employment of a beneficiary, DHS reminds petitioners of their obligation to file new or amended petitions where appropriate and their ability to withdraw petitions where appropriate. *See* 8 CFR 214.2(h)(11)(i)(A), (iii)(A)(*1*).

DHS would also like to clarify that providing start date flexibility does not impact the beneficiary's status when multiple petitions are filed but is a narrow revision codifying current practice that allows a later start date when there are multiple rounds of selection, and the petition filing window extends beyond October 1. As explained in the NPRM, other restrictions on the petition start date will remain in place, such as the requirement that a petition may not be filed earlier than 6 months before the date of actual need. *See* 8 CFR 214.2(h)(2)(i)(I).

Comment: A few commenters indicated that DHS should not allow more than one petition per beneficiary. A commenter requested that DHS provide, in regulation, a process that USCIS would allow only one petition per beneficiary to be filed at a time, which would reduce the risk of multiple filings and prevent unnecessary use of USCIS resources. Under this process, if a petition is denied other than due to fraud or misrepresentation, a selected beneficiary could then pursue H–1B status through other employers that submitted registrations on their behalf. Another commenter noted that ''allowing multiple petitions would result in unnecessary inefficiencies for both USCIS and petitioning employers.''

Response: With respect to the suggestion that DHS restrict the petition filing process to one total petition per beneficiary, DHS declines to make this change. Under current practice, the filing of multiple petitions for the same beneficiary has always been a possibility, and the beneficiary centric process is not designed to change this practice.

Section 214(g)(7) of the INA, 8 U.S.C. 1184(g)(7), specifically contemplates that more than one petition can be filed for a beneficiary (''Where multiple petitions are approved for 1 alien, that alien shall be counted only once''). Thus, such a limitation may not be consistent with that statute. DHS also acknowledges that there could be legitimate reasons for an individual to have more than one petition filed by different petitioners on their behalf.

D. Start Date Flexibility for Certain H–1B Cap-Subject Petitions

Comment: Multiple commenters expressed broad support for the proposal to permit start date flexibility for certain H–1B cap-subject petitions, with one stating that the change to permit requested start dates on or after October 1 of the relevant fiscal year will benefit F–1 students and universities and another stating that the change ''codifies the elimination of a confusing ''trap'' for ''visa lottery'' H–1B visa petitioners.'' One commenter asked the agency to explicitly provide start date flexibility in situations where a requested validity period ends before the petitioner receives the approval notice.

Response: DHS agrees with the comments that providing start date flexibility for certain H–1B cap-subject petitions will be beneficial in many ways. As stated in the NPRM, this

proposal will align the regulations related to H–1B cap-subject petitions with current USCIS practice, which is to permit a requested petition start date of October 1 or later, as long as the requested petition start date does not exceed 6 months beyond the filing date of the petition. 88 FR 72870, 72888, 72898 (Oct. 23, 2023). The request to provide start date flexibility in situations where a requested validity period ends before the petitioner receives the approval notice does not align with the changes that DHS proposed in the NPRM about the start date, which was to remove the language at 8 CFR 214.2(h)(8)(iii)(A)(*4*) that limited the requested start date when filing a cap-subject petition. Rather, this request aligns with the proposed ''Validity Expires Before Adjudication'' provision at 8 CFR 214.2(h)(9)(ii)(D)(*1*) of the NPRM. DHS is not finalizing that provision in this rule. The start date flexibility provision relates only to the flexibility in start date that petitioners may use on cap subject H–1B filings, as described in the NPRM, allowing start dates after October 1 of the applicable fiscal year.

E. Registration Related Integrity Measures

1. Bar on Multiple Registrations and Petitions Submitted by Related Entities Without a Legitimate Business Need

Comment: Some commenters expressed general support for the bar on multiple registrations submitted by related entities at proposed 8 CFR 214.2(h)(2)(i)(G). A few commenters wrote that the proposed bar would help reduce fraud and exploitation of the selection process. Additionally, a few commenters reasoned that the proposed provision would promote equity and fairness in the selection process, noting that the proposed provision mirrors the existing restrictions on filing multiple cap-subject petitions. Furthermore, a commenter remarked that the proposal would reinforce legitimate business needs as the basis for selection.

Response: DHS appreciates the commenters' feedback but has decided not to finalize the proposed bar on multiple registrations submitted by related entities at this time, although DHS intends to address and may finalize this proposed provision in a subsequent final rule. While the intention behind this provision is to reduce fraud in the selection process, changing the structure of the registration process to a beneficiary centric selection process will reduce fraud and abuse of the registration process and more time and data will help inform the utility of this proposed provision.

Comment: A commenter applauded the change to a beneficiary centric registration system but opined that this change ''makes unnecessary any requirement that related entities prove a legitimate business need to file multiple petitions for the same beneficiary'' under current 8 CFR 214.2(h)(2)(i)(G). The commenter ''urge[d] USCIS to delete the portion of 8 CFR 214.2(h)(2)(i)(G) dealing with related entities in its entirety.'' Other commenters similarly questioned the need to restrict multiple petitions by related entities under the beneficiary centric system, with one commenter stating that, in reality, some related entities are so large that they do not communicate and/or coordinate workforce issues with each other.

Response: DHS declines to make any changes to current 8 CFR 214.2(h)(2)(i)(G) at this time. DHS did not propose to eliminate or alter current 8 CFR 214.2(h)(2)(i)(G) with respect to multiple petitions by related entities without a legitimate business need. As stated in the NPRM, if registration were suspended, this bar on multiple petitions would remain relevant. 88 FR 72888, 72900 (Oct. 23, 2023). Even when registration is required, and even with the change to a beneficiary centric selection process, DHS believes that the bar on multiple H–1B cap petitions by related entities without a legitimate business need remains an integrity measure to guard against related entities filing multiple petitions without a legitimate business need simply to increase their chances of getting an approval and resulting cap number/exemption for the selected beneficiary. While unrelated entities would likely not be working together and would have no incentive to file multiple H–1B cap petitions for the same beneficiary without a legitimate business need, related entities would have an incentive to work together to file multiple H–1B cap petitions for the same beneficiary simply to increase their chances of getting an approval for that beneficiary. While the new beneficiary centric selection process will likely eliminate the incentive for related entities to game the system to increase the odds of selection at the registration stage, DHS does not believe that the beneficiary centric selection process will eliminate or significantly impact the incentives to game the system to increase the odds of approval at the petition stage that currently exist and are mitigated by the existing regulation. Thus, DHS disagrees with the commenters that the beneficiary centric selection process will render the bar on multiple petitions by related entities at current 8 CFR 214.2(h)(2)(i)(G) unnecessary.

DHS acknowledges that the existing ''related entities'' and ''legitimate business need'' standards place some evidentiary burden on petitioners. However, removing those limitations would essentially allow all petitioners to file multiple H–1B cap petitions for the same beneficiary without any restrictions. DHS believes the existing burdens to petitioners are outweighed by the increased risk of gaming that removing all restrictions on multiple H–1B cap petitions by related entities, absent a legitimate business need, would pose.

Comment: A commenter stated that DHS should eliminate the portion of proposed 8 CFR 214.2(h)(2)(i)(G) which discusses ''related entities'' because, in part, the terms ''related entities'' and ''legitimate business need'' used in the provision are ambiguous, unworkable, and likely to contribute unnecessarily to agency backlogs.

Response: The existing prohibition on related entities filing multiple petitions for the same beneficiary at 8 CFR 214.2(h)(2)(i)(G) remains. DHS is not making any changes to existing 8 CFR 214.2(h)(2)(i)(G), noting that the terms ''related entities'' and ''legitimate business need'' in the provision are not new terms and that USCIS issued policy guidance on these terms in *Matter of S-Inc.,* Adopted Decision 2018–02 (AAO Mar. 23, 2018).

2. Registrations With False Information or That Are Otherwise Invalid

Comment: A couple of commenters expressed support for codifying the ability for USCIS to deny H–1B petitions or revoke approved petitions on the basis that it includes a false attestation. The commenters said this change showed the importance of accuracy and honesty in the registration system and would make the system more resilient and dependable in resisting fraudulent activity.

Response: DHS agrees with the commenters that codifying the ability for USCIS to deny or revoke H–1B petitions that provide untrue, incorrect, inaccurate, or fraudulent statements of fact, or misrepresent material facts, including providing false attestations on the registration, will improve the integrity of the registration system.

Comment: A few commenters expressed concern with extending regulations on denials and revocation of H–1B petitions for statements on petitions that are ''inaccurate, fraudulent, or misrepresented a material fact'' to information provided in the

registration, particularly with respect to typographical errors. For instance, a commenter expressed concern with USCIS expanding the regulations at proposed 8 CFR 214.2(h)(10)(ii), (h)(11)(iii)(A)(2), stating that this expansion would allow ''automatically denying or revoking H–1B petitions due to inaccurate information contained on a registration'' and would not allow a petitioner an opportunity to correct an unintentional typographical error. The commenter recommended changes to the regulatory text at 8 CFR 214.2(h)(8)(iii)(D)(*1*) to codify that USCIS may excuse typographical errors on a registration in its discretion when ''the H–1B petition [is] supported by relevant identity documents and where [the] petitioner satisfies USCIS that the inaccuracy was unintentional and did not create any advantage in the lottery selection.'' A few commenters stated that the final rule should permit some ability to correct typographical, non-substantive errors, with one commenter requesting DHS amend the regulatory text to specifically state that USCIS may excuse typographical errors on a registration in its discretion. One of these commenters also requested that DHS allow officer discretion regarding permissible changes to identifying information rather than an exhaustive list of scenarios in which the change will be acceptable. Another commenter stated that automatically denying or revoking H–1B petitions solely due to typographical errors in the registration is inconsistent with current USCIS policy. Another commenter stated that the regulatory provision does not clearly indicate how USCIS will review and accept petitions that have explainable discrepancies and said that the regulations should explicitly state that USCIS will issue a receipt for a petition with discrepancies, which would provide the petitioner with an opportunity to address and explain any disparities.

Response: DHS first notes that USCIS does not, and would not, automatically revoke a petition under 8 CFR 214.2(h)(11)(iii), as that paragraph pertains to revocation on notice. *See* 8 CFR 214.2(h)(11)(iii) (''Revocation on notice''). Thus, the proposed provision at 8 CFR 214.2(h)(11)(iii)(A)(*2*), as finalized by this rule, clearly provides for revocation upon notice. Regarding denials, the addition of the beneficiary centric selection process to the regulation at 8 CFR 214.2(h)(10)(ii) will not change the operation of that regulation or USCIS policy that generally provides for notice and an opportunity to respond prior to the denial of a petition.

DHS will not adopt the suggestions to expressly codify that a ''typographical error'' may be a permissible change in identifying information in some circumstances at 8 CFR 214.2(h)(8)(iii)(D)(*1*), nor will it adopt any of the other related changes suggested by the commenters. DHS believes these changes are unnecessary. USCIS has not changed its position that it will not automatically reject the Form I–129 petition for typographical errors on the selected registration in comparison with the Form I–129.[16] The burden remains on the registrant/petitioner to confirm that all registration and petition information is correct and to establish that the H–1B cap petition is based on a valid registration submitted for the beneficiary named in the petition and selected by USCIS.[17] Also, USCIS adjudicators already have the ability to exercise discretion after allowing the petitioner to explain a mismatch in identifying information. The NPRM made clear that ''USCIS would typically afford the petitioner the opportunity to respond when identifying information provided on the registration does not match the information provided on the petition, and petitioners would need to be prepared to explain and document the reason for any change in identifying information. In its discretion, USCIS could find that a change in identifying information is permissible.'' 88 FR 72870, 72898 (Oct. 23, 2023). The phrase ''could include, but would not be limited to'' in new 8 CFR 214.2(h)(8)(iii)(D)(*1*) already makes clear that the listed circumstances are examples, not an exhaustive list.

Additionally, when entering submissions in the registration tool, registrants and their representatives are given the opportunity to review the data entered before submitting, giving them ample time to double-check what is entered. Furthermore, registrants and their representatives have until the close of the registration period to correct any errors they may have made on a registration. As stated in the final registration rule, ''USCIS will allow petitioners to edit a registration up until the petitioner submits the registration. A petitioner may delete a registration and resubmit it prior to the close of the registration period.'' 84 FR 888, 900 (Jan. 31, 2019). Thus, DHS believes registrants already have sufficient opportunities to identify and correct typographical errors.

Finally, codifying language in the regulation about typographical errors in a registration may invite false claims of ''typographical error,'' in an attempt to game the beneficiary centric registration process by trying to make one beneficiary appear as two different beneficiaries. DHS, therefore, will not adopt the commenter's suggestion because codifying an exception for typographical errors could undermine the other changes being made in this final rule to limit the potential for abuse and gaming of the registration system and better ensure that each beneficiary has the same chance for selection.

Comment: A commenter suggested DHS ''expressly add an intent requirement, or otherwise clarify the need for intentionality, before revocation is considered,'' because there can be ''several innocent reasons why a registration may be technically inaccurate.''

Response: DHS does not believe it is necessary to introduce a requirement of intent to this provision. DHS believes registrants already have sufficient opportunity to address inaccuracies in information submitted in the registration process. As stated above, new 8 CFR 214.2(h)(11)(iii)(A)(*2*) provides for revocation upon notice and the addition of registration to the regulation at 8 CFR 214.2(h)(10)(ii) does not change the operation of that regulation or USCIS policy that generally provides for notice and an opportunity to respond prior to the denial of a petition. USCIS adjudicators already have the ability to exercise discretion after allowing the petitioner to explain a mismatch in identifying information.

Further, introducing a requirement of intent may needlessly complicate and delay adjudication. DHS believes that the regulatory framework, as proposed and finalized by this rule, sufficiently affords the ability to explain inaccuracies in the registration process.

Comment: While discussing proposed 8 CFR 214.2(h)(8)(iii)(D)(*2*), a joint submission from a professional association and an advocacy group suggested that the proposed section be either removed or amended, reasoning there was potential for ''significant issues'' with the payment mechanism during the registration process. Referencing issues associated with the Department of Treasury's ''*Pay.gov*'' site, the commenters expressed concern that H–1B registrations could be rejected in situations where payment issues resulted from system issues, rather than

[16] USCIS, ''H–1B Electronic Registration Process,'' *https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations-and-fashion-models/h-1b-electronic-registration-process* (last updated July 31, 2023).

[17] *Id.*

user error. The commenters urged USCIS to ''make every reasonable effort'' to communicate with petitioners upon a payment issue being discovered so that it could be resolved and proposed ''specific changes'' to the notification process associated with payment issues, including an email notification and a grace period following notification of a payment issue. A different commenter, while generally supportive of proposed 8 CFR 214.2(h)(8)(iii)(D)(2), similarly requested a ''notice and response process prior to denial or revocation of a petition'' for invalid fees in recognition that ''simple banking or other administrative errors could lead to unreconciled fees that do not reflect fraud or abuse of the system.''

Response: DHS thanks the commenters for their feedback. However, DHS declines to adopt the commenters' suggestions to allow a period of time to cure a deficient registration payment at the time of petition filing, or to provide in all cases a notice and response process prior to denying or revoking a petition. Proper submission of the registration is an antecedent procedural requirement to properly file the petition. Allowing a petition to be filed based on a registration with a deficient payment could create a framework in which there is little incentive to properly pay for any registration until it is selected, and a petition based on that registration is being filed. It would not be feasible to investigate in all cases whether a failed payment was truly in error or specifically done to delay paying the registration fee until that registration was selected and a petition filed. This would undermine the current fee structure that supports the registration system development, supporting services and maintenance.

Allowing a registration with a deficient payment to be cured after selection could lead to an avenue to abuse the registration system. Currently, registrations that are designated as having a failed payment are not included in the H–1B cap selection process. If the suggested regulatory language were adopted, USCIS would have to include those registrations with a failed payment in the selection process (in order to properly give registrants the suggested 10 days to cure any payment deficiencies). As indicated above, this could lead to opportunities to abuse the system by simply delaying payment for all registrations until after the selection process is completed and then only paying for those that are selected. It could also mean that those registrations that truly failed payment would still be included in selection. This could lead to the selection of more registrations that would not be followed by a petition filing, thus increasing the difficulty in administering the cap.

It is also operationally burdensome to collect the registration fee at the time of petition intake or in response to a request for evidence (RFE) or notice of intent to deny (NOID) on that petition. Requiring USCIS to manually process these payments upon petition intake via check or credit card payment (as opposed to the automated Pay.gov payment system in place at the time of registration) would not be operationally efficient and would require USCIS to incur additional expenses, as USCIS incurs a cost any time it must process additional payments or issue additional RFEs or NOIDs.

DHS also will not currently adopt the suggestions to modify the registration system itself to further notify registrants of the status of their payments due to current system limitations and requirements. The registration system will notify registrants that payment has been initially processed. The registration system will also show the status of the registration as ''Invalidated-Failed Payment'' once USCIS identifies that the payment has failed, and USCIS will send registrants an email or SMS text to log into their account and check for updates. Additionally, payees can proactively confirm the status of a payment by contacting their bank, credit card company, or payment service, and confirm payment generally by the next business day, if not before.[18] Thus, payees already have ways to confirm payment status at the registration stage and proactively take steps to remedy payment issues. Regardless, USCIS will consider options to display additional payment information within the registration system in the future.

Comment: A couple of commenters expressed support for the proposal to add invalid registration as a ground for revocation, reasoning it showed the importance of honesty and accuracy in the registration process. A commenter added that the proposal would help to ensure the dependability and resiliency of the selection process against fraudulent practices. Another commenter expressed general support for extending the grounds of denial or revocation to expressly include registrations with false information or that are otherwise invalid. This commenter also expressed general support for the beneficiary centric process and the bar on multiple registrations submitted by related entities, reasoning that limiting the number of ''false'' registrations would make the registration process more manageable and reduce USCIS' workload.

Response: DHS agrees with these commenters and anticipates that this rule will enhance the fairness and integrity in the registration process. As explained in the NPRM, to allow companies to provide false information on the registration without consequence would allow them to potentially take a cap number for which they are ineligible.

3. Other Comments and Alternatives to Anti-Fraud Measures Related to Registration

Comment: Numerous commenters provided general comments on fraud in the H–1B registration system and advocated for general improvements to mechanisms for identifying and preventing abuse. Multiple commenters generally discussed the need for anti-fraud measures to address abuse in the registration system, stating that changes are needed to promote fairness and integrity of the H–1B visa program, preserve the reputation and transparency of the U.S. immigration system, protect U.S. workers, allow skilled foreign professionals to stay in the United States and contribute to the economy, and ensure the number of registrations aligns with available job openings and the needs of the country.

Response: DHS remains committed to deterring and preventing abuse of the registration process and to ensuring only those who follow the law are eligible to file an H–1B cap petition. To this end, USCIS has already undertaken extensive fraud investigations, denied and revoked petitions accordingly, and continues to make law enforcement referrals for criminal prosecution. USCIS has also increased messaging reminding the public that at the time each registration is submitted, each prospective petitioner is required to sign an attestation, under penalty of perjury, that: all of the information contained in the registration submission is complete, true, and correct; the registration(s) reflects a legitimate job offer; the registrant intends to file a petition if selected; and the registrant has not worked with others to unfairly increase the chance of selection.[19] In finalizing

[18] Pay.gov, ''Frequently Asked Questions,'' *https://www.pay.gov/WebHelp/HTML/faqs.html* (payments from bank accounts will be charged the next business day; credit and debit card payments are visible within 24 hours; payments through a payment service are charged according to the service's schedule). (Last visited January 9, 2024.)

[19] USCIS, ''H–1B Electronic Registration Process,'' *https://www.uscis.gov/working-in-the-united-states/*

Continued

the proposed regulatory text at 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(*2*), DHS reiterates that submitting false or incorrect information on the registration, including false attestations, is grounds for denial or revocation of the approval of the petition.

Additionally, in changing to the beneficiary centric registration, multiple frivolous registrations that may not represent legitimate bona fide jobs will no longer increase an individual's chances of being selected. As such, the beneficiary centric selection will remove the incentive to have multiple registrations solely to increase selection chances.

Comment: Many commenters voiced concern over frivolous registrations and fraud in the H–1B selection process, specifically the use of fraudulent companies to submit registrations and registrations from individuals without valid job offers.

Many of these commenters stated that the proposed changes do not go far enough and urged USCIS to bar certain types of entities from submitting registrations and/or invalidate certain types of registrations prior to running the lottery. These commenters stated that USCIS should:

- Block speculative entries from being considered in the selection process;
- Stop individuals from using fake job offers to register by closing loopholes that allow companies to submit registrations for individuals without valid job offers;
- Require beneficiaries working for consulting companies or third-party contractors to have valid client job offers;
- Implement a verification process for registrants, beneficiaries, documents (such as passports), and/or job offers at registration;
- Increase the transparency, oversight, reporting, and auditing of the selection process;
- Ban beneficiary-owners from submitting registrations or limit registrations from beneficiary-owners to only those who can demonstrate legitimate work; and
- Screen potential registrants for certain labor and employment law violations and disputes and prohibit any employer with recent or ongoing labor violations or disputes from participating in the H–1B registration process.

Response: DHS is unable to invalidate or bar certain registrations, such as registrations that are deemed frivolous or submitted by certain types of companies, at the registration stage because that would require USCIS to adjudicate the underlying registration. USCIS does not adjudicate a registration. Further, the registration process is not the stage at which USCIS assesses the veracity of documents, the bona fides of the job offer, or other aspects of the offered position. As previously stated in the NPRM, submission of the registration is merely an antecedent procedural requirement to properly file an H–1B cap-subject petition and is not intended to replace the petition adjudication process or assess the eligibility of the beneficiary for the offered position. 88 FR 72870, 72899 (Oct. 23, 2023). Additionally, as noted above, the beneficiary centric registration removes the incentive for a beneficiary to have multiple registrations solely to increase their chance of selection, which DHS anticipates will reduce the number of frivolous registrations.

Comment: To reduce frivolous registrations, a few commenters suggested requiring additional information on the registration, such as: requiring companies to submit job offer letters, job descriptions, and documentation during registration; asking employers to provide full LCAs at the time of initial registration; and requiring registrants to document that it has a non-speculative position in a specialty occupation for the beneficiary as of the start date of the validity period requested on the registration.

Response: Beyond requiring valid passport or travel document information for the beneficiary on the registration, DHS is not requiring additional new information on the registration at this time. DHS does not believe that requesting additional information about the beneficiary, the petitioner, or the underlying job offer or position, is necessary to effectively administer the registration system. Some of the additional information proposed by commenters (such as information about the job offer) is information that USCIS would require and review to determine eligibility in the adjudication of the H–1B petition. Establishing eligibility is not a requirement for submitting a registration. USCIS believes the change to require valid passport information or valid travel document information is sufficient to identify the beneficiary and reduce potential fraud and abuse of the registration system.

Comment: Several commenters noted continuing concerns with the registration process and advocated for increased penalties to prevent further fraud and abuse, including:

- Review and investigate companies and beneficiaries who abused the H–1B system in previous years;
- A ban, such as for 5 or 10 years, for companies and beneficiaries who engage in fraudulent activities;
- A 10-year ban for beneficiaries and companies that do not file a petition after being selected;
- Charge fines to employers found to have flooded the registration process with frivolous registrations and collect additional fees from registrants to pass a portion of these fines and additional fees directly to the Department of Labor to fund their investigation and enforcement activities in the H–1B program;
- At the registration stage, audit all registrants with more than ten registrations and debar registrants found to have engaged in registration fraud;
- Revoke H–1B visas for those who have previously exploited the system; and
- Implementing consequences for companies that abuse the registration process and impose stricter penalties for those found guilty of abuse.

Response: DHS has undertaken efforts to deter abuse of the registration system and to ensure that those who abuse the registration system are not eligible for H–1B cap petition approval. As noted previously, in finalizing the proposed regulatory text at 8 CFR 214.2(h)(10)(ii) and (11)(iii)(A)(*2*), DHS reiterates that submitting false or incorrect information on the registration, including false attestations, is grounds for denial or revocation of the approval of the petition. If USCIS has reason to believe that the attestations made during registration are not correct, it will investigate the parties in question, including examining evidence of collusion and patterns of non-filing of petitions. Where appropriate, USCIS will deny or revoke the approval of petitions where the attestations made at the registration stage are found to be false, including making findings of fraud or willful material misrepresentation against petitioners, if the facts of the case support such findings.

Regarding the suggestions that USCIS audit companies with 10 or more registrations, fine or ban certain companies from participating in the registration process after being found to have engaged in registration fraud, and charge additional fees to support investigations and enforcement activities, DHS declines these suggestions. DHS does not think that companies that submit more than a certain number of registrations for different beneficiaries necessarily

temporary-workers/h-1b-specialty-occupations-and-fashion-models/h-1b-electronic-registration-process (last updated July 31, 2023).

warrant investigation as many companies, and in particular large companies, may have a legitimate need to hire multiple H–1B beneficiaries. Requiring USCIS to audit companies that properly submit more than a certain number of registrations would be an ineffective use of resources and would take resources away from pursuing investigations that are more likely to uncover fraud and abuse. In addition, the H–1B registration process moves quickly and USCIS does not adjudicate a registration at the registration stage. Further, as explained in the NPRM,[20] USCIS has examined patterns in the registration process and has investigated companies based on evidence suggesting that they were attempting to game the system. However, blocking or fining employers from participating in the H–1B registration process goes beyond what DHS proposed in the NPRM. This suggested alternative would take significant time and agency resources and would be insufficient to address the issues with the current registration process that DHS anticipates the beneficiary centric selection process will successfully address. In addition, as DHS indicated in the 2019 registration final rule, there may be monetary fines/criminal penalties under 18 U.S.C. 1001(a)(3) which apply generally to statements/representations made to the Federal Government, and registrants that engage in a pattern and practice of submitting registrations for which they do not file a petition following selection may be referred for investigation of potential abuse of the system.[21] USCIS will continue to investigate and hold bad actors accountable to the extent of its authority, including making law enforcement referrals for criminal investigation.

Finally, with respect to the suggestion that DHS impose an additional registration fee to further fund investigations and enforcement in the H–1B program, DHS did not propose to increase the H–1B registration fee in the H–1B NPRM, and any such proposal would need to be subject to public notice and comment before being finalized. As discussed elsewhere in this rule, DHS did propose to increase the H–1B registration fee in the Fee Rule NPRM.[22] Any fee increase resulting from the Fee Rule NPRM proposal would be addressed in a separate final rule that may be issued based on that separate regulatory proposal. In addition, DHS may address any subsequent registration fee increase in future rulemaking.

F. Other Comments Related to the Proposed Registration System

1. Electronic Registration vs. Paper-Based Filing

Comment: A few commenters recommended improving the current registration system and/or enhancing online filing capabilities instead of reverting to the paper-based filing system. An individual commenter stated that reverting to a paper-based system increases the risk of human error, makes it challenging to identify unique individuals, and increases vulnerabilities to manipulation and bribery.

Response: DHS does not intend to revert to a paper-based system and intends to conduct the electronic registration process for the FY 2025 cap season.[23] As noted in the NPRM, DHS considered the alternative of eliminating the electronic registration system and reverting to the paper-based filing system stakeholders used prior to implementing registration, but ultimately determined that the benefits of having an electronic registration system still outweigh the costs and any potential problems caused by frivolous filings. DHS proposed changes to the registration system to mitigate the potential for frivolous filings and is now finalizing those changes, with some modifications to the NPRM as discussed above.

Comment: A commenter stated that if the new beneficiary centric registration process cannot be implemented in time for the FY 2025 cap season, ''USCIS must indeed go back to the old system of paper filings to preserve its credibility and the credibility of its H–1B program as a whole.''

Response: DHS does not intend to revert to a paper-based system and intends to conduct the electronic registration process, with beneficiary centric selection, for the FY 2025 cap season.

2. Comments on Fees Related to Registration

Comment: Multiple commenters discussed the current $10 registration fee. Several commenters stated that USCIS' decision to implement a $10 registration fee has increased fraud in the registration system by incentivizing individuals to provide false employment information. Another commenter stated that the registration fee of $10 renders the limited number of available visas insufficient to meet the demand at that price. Several commenters suggested that USCIS increase fees or change fee collection to discourage fraud, for example:

- A fee increase of approximately $500 to $1,000 per registration;
- Implementing a requirement to pay the Fraud Prevention and Detection fee of $500 along with a new filing fee of $215;
- Increasing fee from ten dollars ($10) to $215, per the FY 2022/2023 fee rule;
- Require a ''large'' deposit that is refundable; and
- Increase registration fees to allow only ''serious companies'' to submit registrations.

Response: DHS did not propose to increase registration fees in the October 23 NPRM. Because DHS did not propose any changes to the H–1B registration fee in this rulemaking, these comments are outside the scope of this rulemaking. However, on January 4, 2023, DHS published an NPRM to adjust certain immigration and naturalization benefit request fees. 88 FR 402 (Jan. 4, 2023). In that NPRM, DHS proposed, among other things, to increase the H–1B registration fee from $10 to $215. The comment period for the proposed rule closed on March 13, 2023. DHS received nearly 8,000 comments in response to the NPRM, including comments relating to the proposed increase in the H–1B registration fee. Many of the comments received in response to the proposed fee rule relating to the proposed increase in the H–1B registration fee were similar to the comments submitted here. DHS will soon issue a rule to finalize its adjustment to immigration and naturalization benefit request fees, including the H–1B registration fee. Public comments on the increase in the H–1B registration fee can be found in the Fee rule NPRM rulemaking docket, and the responses to those comments will be in the Fee final rule.

Comment: A few commenters said that USCIS should collect upfront all filing fees for the Form I–129 petition to deter fraudulent registrations. USCIS would then refund the petition filing fees to those whose registrations were not selected.

Response: DHS declines to adopt the commenters' suggestions to collect petition filing fees at time of registration. Petition filing fees will be collected when the petition is filed,

[20] 88 FR 72870, 72889 (Oct. 23, 2023) (''DHS continues to take steps against potential abuse and is in the process of investigating potential malfeasance and possible referrals to law enforcement agencies.'').

[21] 84 FR 888, 904 (Jan. 31, 2019).

[22] 88 FR 402, 500–501 (Jan. 4, 2023).

[23] But note that the current regulations provide USCIS with the discretion to suspend the H–1B registration process, and revert to a paper-based selection process, in the event it determines that the H–1B registration process is inoperable for any reason. 8 CFR 214.2(h)(8)(iv). DHS did not propose changes to this process, and this option remains available to USCIS.

consistent with current practice. DHS does not view registration as the same as filing a petition because the submission of the registration is merely an antecedent procedural requirement to properly file an H–1B cap-subject petition. DHS also cannot adopt the suggestions to require petitioners to include petition filing fees at the time of registration due to current system limitations and requirements. Requiring USCIS to refund or hold funds would not be operationally efficient and would require USCIS to incur additional expenses, as USCIS incurs a cost any time it is required to refund a fee to an applicant or petitioner. 84 FR 888, 903–904 (Jan. 31, 2019).

3. Other Comments and Alternatives Related to Registration

Comment: A couple of commenters generally supported the beneficiary centric changes to the registration process but indicated that these changes do not adequately address the ''increasing demand for talent in the U.S. economy'' or the ''ever growing need for more H–1B talent in the U.S.'' One of these commenters said that DHS should work with lawmakers to increase the annual cap. Another commenter indicated that the significant increase in registrations in the past few lotteries effectively resulted in those who did not submit multiple registrations being ''penalized for not engaging in fraud.'' This commenter suggested that, in addition to the beneficiary-based selection, USCIS should consider temporarily increasing the number of registrations it selects to help compensate those who were unfairly disadvantaged during the last few lotteries.

Response: The change to a beneficiary centric selection process is intended to address issues related to fairness and integrity of the selection process, not issues related to labor demand or raising the statutory cap. Congress set the current annual regular H–1B cap at 65,000 and the annual H–1B advanced degree exemption at 20,000. DHS does not have the statutory authority to increase—even temporarily—these congressionally mandated caps.

Regarding the suggestion to temporarily raise the number of selected registrations, USCIS already takes into account historical data related to approvals, denials, revocations, and other relevant factors when calculating the number of registrations projected as needed to meet the statutory numerical allocations; and, if necessary, USCIS may increase those numbers throughout the fiscal year. *See* 8 CFR 214.2(h)(8)(iii)(E). In fact, USCIS has generally increased the total number of registrations it has selected for each fiscal year since the implementation of the registration system.[24] Therefore, DHS declines to make any changes as a result of these comments but will continue to rely on data and all relevant information when projecting how many registrations to select toward the 65,000 statutory numerical limitation and the 20,000 advanced degree exemption.

Comment: A few commenters offered suggestions for alternative forms of relief for F–1 students or other prospective beneficiaries who were disadvantaged in prior lotteries. Without elaborating, a commenter stated that the NPRM failed to address the concerns of F–1 students impacted by fraudulent activities in the past 3 years and that DHS should provide ''alternative relief options for genuine candidates facing uncertainties.'' Another commenter suggested that DHS should offer an employment authorization document ''as a form of compensation'' for individuals who were not selected following H–1B registration periods in prior years. While not specific to F–1 students who were disadvantaged in prior lotteries, a commenter requested DHS to consider extending cap-gap to all F–1 OPT or STEM OPT students registered in the H–1B lottery until USCIS concludes the lottery selection process for the fiscal year.

Response: As previously noted, changing the registration process to a beneficiary centric system is intended to address issues related to fairness and integrity of the selection process. DHS is not attempting to provide relief or compensate individuals who were not selected in previous registration periods through this regulatory action and declines to adopt these suggestions.

Comment: Multiple commenters suggested that DHS remove the random selection process altogether and instead suggested that the Department select registrations based on particular characteristics. These commenters suggested that the Department:

- Replace the random selection process with a merit-based system;
- Replace the random selection process with a ''percentage auction'' in which employers would bid for H–1B visas;
- Select registrations based on company needs and individual skills;
- Implement a points-based system in place of a random selection system;
- Implement a wage-level/wage or salary amount/income-based prioritization system, including:
  - Wage-based allocation process for employers paying the highest wages/salaries for non-speculative jobs or having terms and conditions of employment set through a collective bargaining agreement;
  - Select registrations based on the highest salaries;
  - Change the random selection process to an income-based system, and remove the lower income levels from the system to prevent outsourcing and displacement of U.S. talent;
  - Automatically select a registration for a job offer above a certain salary;
- Select registrations based on ''virtuous employer behavior'', such as hiring graduates of U.S. universities, sponsoring H–1B workers for permanence, or having terms and conditions of employment set through a collective bargaining agreement;
- Introduce degree-based categorizations in the selection system, reasoning that such an approach would allow more advanced degrees, like Ph.D.s, to have a unique category to align with the specialty-based nature of H–1B visas;
- Work with the Department of Labor (DOL) to identify industries with heavy demand for workers and give those industries priority;
- Provide priority status for U.S. master's students, Ph.D. graduates, and beneficiaries with greater than 10 years of work experience;
- Prioritize registrations based on the duration of the beneficiary's work experience or active full-time employment;
- Increase the chances of selection for individuals residing in the United States relative to those who are outside the country, individuals residing in the United States legally, international students, or U.S. graduates in the United States; and
- Revise the registration system so that it rewards highly motivated individuals who will make ''genuine contributions'' and contribute to the U.S. economy.

Response: In the NPRM, DHS did not propose to prioritize or give preference to any registration based on skills, salaries/wages, education, experience, industry, or any other new criteria. Rather, the goal of this rule is to provide each unique beneficiary with an equal chance of selection. Selecting based on specific characteristics would not

[24] USCIS made a total selection of 124,415 in cap fiscal year 2021, 131,924 in cap fiscal year 2022, 127,600 in cap fiscal year 2021, and 188,400 in cap fiscal year 2024. USCIS, ''H–1B Electronic Registration Process,'' *https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations-and-fashion-models/h-1b-electronic-registration-process* (last updated July 31, 2023).

achieve this goal. DHS declines to implement any of these suggestions.

Comment: A commenter claimed that ''the names of people who are not selected seems to be clustered,'' the random selection process can be biased and can ''screen out people,'' and that ''numbers generated by computers are skewed and prefer specific numbers.''

Response: DHS disagrees with this comment. If USCIS determines it has received enough electronic registrations at the close of the initial registration period to reach the applicable numerical allocation(s), USCIS will randomly select from among the registrations properly submitted during the initial registration period the number of registrations deemed necessary to meet the applicable allocation. As the selection is done via a random selection algorithm, there is no bias or preference for certain registrants over others. The commenter did not provide evidence or cite to data to support their claim that the selection algorithm is biased. As noted above, DHS anticipates that the changes made with this rulemaking will reduce the potential for gaming the registration process and help ensure that each beneficiary has the same chance of being selected.

Comment: A few commenters suggested a ''cap,'' ''quota,'' or other restrictions on registrations for beneficiaries from certain countries, remarking that the current registration system has seen disproportionate representation from nationals of certain countries. A commenter remarked that the proposed changes would allow for fairer opportunities for beneficiaries of various nationalities, rather than beneficiaries from certain countries—the commenter cited USCIS H–1B petition data from 2019 indicating that 74.5 percent of H–1B petition beneficiaries were from India.[25]

Response: DHS declines to adopt a cap, quota, or other restriction on registrations based on a beneficiary's nationality. DHS disagrees with the assertion that a beneficiary's nationality has any relevance to their chance of selection under the registration-based selection process or the beneficiary centric selection process.

Comment: A commenter requested DHS to allow cap-exempt H–1B holders to transition to cap-subject employers without participating in the registration selection process, stating that the current system imposes burdens on both the employee and the prospective employer but also opens the door to potential H–1B program abuses and fraudulent activities, especially by unscrupulous companies that exploit the system through multiple filings and manipulative practices.

Response: DHS declines to adopt this suggestion. The NPRM did not propose to address the issue of cap-exempt H–1B workers transitioning to cap-subject employers. Allowing a cap-exempt H–1B worker to transfer to a cap-subject employer without participating in the registration selection process would violate 8 CFR 214.2(h)(8)(iii)(F)(*5*) which the NPRM did not propose to change, as well as INA sec. 214(g)(6), 8 U.S.C. 1184(g)(6).

Comment: A commenter requested DHS to allow a beneficiary to view the case status of an H–1B registration filed by their employer, stating that this will allow a beneficiary to verify the information provided about them by a prospective employer. Another commenter suggested that registrations should be submitted by the beneficiaries rather than the employers, so that the beneficiaries can review the information first-hand, or alternatively that the beneficiaries co-file with the employer. Conversely, another commenter indicated that they appreciate that USCIS did not change the system to allow beneficiaries to submit their own registrations, noting that it could result in many offshore beneficiaries submitting registrations in hopes of obtaining a job offer after selection.

Response: DHS agrees with the commenter who supported DHS not changing who can submit a registration to include beneficiaries. DHS will not implement a change to allow beneficiaries to submit H–1B registrations. The registration process will continue to be employer-based to align with the petition process. In addition, while DHS incorporated a call for preliminary feedback on the beneficiary notification concept, including the ability to access case status information, DHS is not yet in the position to implement the commenter's suggestions. However, these suggestions will be considered for future action.

Comment: A commenter encouraged DHS to work with the U.S. Department of the Treasury to increase the *Pay.gov* daily credit card transaction limit, stating that the current relatively low limit creates considerable challenges for companies submitting a large volume of registrations, and eliminating or significantly increasing the transaction limit would contribute to the NPRM goals of modernizing the program.

Response: Transaction limits in *Pay.gov* are established by the U.S. Department of the Treasury (''Treasury) and are outside DHS's regulatory authority. Therefore, DHS did not propose to amend these limits in the NPRM and will not make any changes in that regard in this final rule. However, in past years, USCIS actively worked with Treasury outside of this rulemaking to waive/increase transaction limits affecting the H–1B registration process and now intends to request an exemption under recently issued Treasury guidance so that it may process credit card transactions in excess of the current daily and monthly credit card transaction limits. USCIS is moving forward with requesting approval from Treasury to increase the transaction limits from $24,999 to $39,999, and every effort will be made to obtain approval for the increase in time for the initial registration period in March of 2024.

Comment: A commenter recommended changes to the myUSCIS portal so that when it sends the petitioner or an attorney a notification after one or more selections occur, the notification will identify the specific individuals who were selected.

Response: DHS understands that the commenter is asking USCIS to enhance automatic account update alerts to explicitly state what has changed in the online account, such as the specific registrant(s) and/or beneficiary(ies) impacted, when a selection has been made. The intent of these alerts is to prompt each online account holder to log into their account to see the details of the case update and obtain specific information on the pending case. Because each matter is case specific, the details in the issued agency notices is important and carefully crafted to present actionable information as well as protect personally identifiable information. For H–1B registrations, the selection notices posted to the online account present the names of the selected beneficiary and of the prospective petitioner, dates of births, contact information, and tax identification numbers. In contrast, the automated messages sent to account holders' email or by SMS text, as selected by the account holder, are intentionally kept general to protect privacy and prevent any inadvertent disclosure of personal information. DHS, therefore, declines to adopt the commenter's suggestion.

Comment: As a way to improve accountability and program integrity, a commenter recommended DHS provide public disclosure of ''employer and recruiter information at the initial registration stage'' and create ''an active mechanism for public objection and

[25] *See* USCIS, ''H –1B Petitions by Gender and Country of Birth Fiscal Year; 2019,'' *https://www.uscis.gov/sites/default/files/document/data/h-1b-petitions-by-gender-country-of-birth-fy2019.pdf* (Jan. 21, 2020).

comment that will be taken into consideration by those ultimately certifying H–1B petitions.'' Another commenter stated DHS should disclose to the public the names of the companies and information about their use or misuse of the visa program.

Response: DHS will not implement these suggestions at this time. As stated above, submission of the registration is merely an antecedent procedural requirement to properly file an H–1B cap-subject petition and is not intended to replace the petition adjudication process or assess the eligibility of the beneficiary for the offered position. Therefore, because registration submission and selection is not an adjudication, USCIS would not have a mechanism or need to consider public objection and comment in the context of registration selection. The goal of this rule is to provide each unique beneficiary with an equal chance of selection. It is not clear from the comment how creating a system of public disclosure and mechanisms for public objection to registrations would help to achieve this goal. Finally, with respect to the suggestion that DHS disclose to the public the names of the companies and information about how they are using the program, it is not clear from the comment whether this suggestion is limited to the H–1B registration process or the H–1B program more broadly. It is also not clear what the commenter meant by ''how companies are using the visa program.'' DHS notes that it already has an H–1B Data Hub [26] where members of the public can search H–1B program information, including employer names, NAICS codes, and geographic information to better understand how the H–1B program is being used, and that third parties may already report alleged fraud or abuse in the H–1B program through an online tip form.[27] As such, DHS will not adopt the suggestions at this time.

IV. Severability

The provisions of this rule are severable from each other such that if a court were to hold that any provision is invalid or unenforceable as to a particular person or circumstance, the rule would remain in effect as to any other person or circumstance. Specifically, DHS intends that the provisions governing the beneficiary centric selection process in paragraph (h)(8)(iii), the elimination of the requirement that the requested start date for the beneficiary be the first day for the applicable fiscal year in (h)(8)(iii)(A)(*4*), and the provisions governing the denial or revocation of H–1B petitions based on inaccurate, fraudulent, or misrepresented material facts in the H–1B petition, H–1B registration, or LCA, or in the case of H–2A and H–2B petitions, the TLC, in paragraphs (h)(10)(ii) and (iii), and (h)(11)(iii), respectively, published in this rule to be severable from one another. As explained throughout this preamble, the beneficiary centric selection process is intended to ensure the fairness in the H–1B selection process by evening out the odds for the selection of H–1B beneficiaries by significantly reducing incentives for the submission of multiple non-meritorious registrations for the same beneficiary. Further the removal of the requirement that a requested start date for the beneficiary be the first day of the applicable fiscal year (*i.e.,* October 1st) is also a stand-alone provision that can operate independently of the other provisions of this rule. Codifying the authority for USCIS to deny or revoke petitions based on false statements made on the H–1B registration will further ensure that the H–1B selection process is based on information that is true and correct.[28] While these provisions, taken together, will provide maximum benefit with respect to making the H–1B registration and cap selection process more equitable while ensuring the integrity of the H–1B registration process and H–1B program more broadly, the beneficiary centric selection process provisions are not interdependent with the provisions providing for denial and revocation of H–1B petitions, and are able to operate separately. Similarly, the expansion of the denial provision to cover false statements on the TLC relates to the integrity of the H–2A and H–2B programs and is independent from and severable from the H–1B program, and the H–1B beneficiary centric selection process.

V. Statutory and Regulatory Requirements

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

Executive Orders (E.O.) 12866 (Regulatory Planning and Review), as amended by Executive Order 14094 (Modernizing Regulatory Review), and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if a regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Office of Management and Budget (OMB) has designated this final rule a ''significant regulatory action'' as defined under section 3(f) of E.O. 12866, as amended by Executive Order 14094, but it is not significant under section 3(f)(1) because its annual effects on the economy do not exceed $200 million in any year of the analysis. Accordingly, OMB has reviewed this final rule.

Summary

The purpose of this rulemaking is to amend the regulations relating to the H–1B registration selection process. Through this rule, DHS is implementing a beneficiary centric selection process. Instead of selecting by registration, USCIS will select registrations by unique beneficiary. Each unique beneficiary who has a registration submitted on their behalf will be entered into the selection process once, regardless of how many registrations are submitted on their behalf. If a beneficiary is selected, each registrant that submitted a registration on that beneficiary's behalf will be notified of selection and will be eligible to file a petition on that beneficiary's behalf

[26] *See* USCIS, ''H–1B Employer Data Hub,'' *https://www.uscis.gov/tools/reports-and-studies/h-1b-employer-data-hub* (last visited Jan. 2, 2024).

[27] *See* USCIS, ''Combatting Fraud and Abuse in the H–1B Visa Program,'' *https://www.uscis.gov/scams-fraud-and-misconduct/report-fraud/combating-fraud-and-abuse-in-the-h-1b-visa-program#H-1B%20Fraud%20and%20Abuse%20Indicators.* Under the heading ''Reporting Suspected H–1B Fraud or Abuse,'' USCIS states: ''Anyone (including American workers and H–1B workers who suspect they or others may be the victim of H–1B fraud or abuse) can send us tips, alleged violations, and other relevant information about potential fraud or abuse using our online tip form.'' (Last visited Jan. 2, 2024.)

[28] As proposed, and made final in this rule, the denial provision in 8 CFR 214.2(h)(10)(ii) is also being expanded to cover false statements on the Department of Labor's TLC (applicable to H–2A and H–2B programs), and the LCA, and the revocation provision in 8 CFR 214.2(h)(11)(iii) is being expanded to include revocation based on false statements made in the LCA. As explained in the NPRM, this would codify DHS's current practices, as the LCA is incorporated into and considered part of the H–1B petition, just like the TLC is incorporated into and considered part of the H–2A or H–2B petition. *See* 88 FR 72870, 72903 (Oct. 23, 2023). These changes to 8 CFR 214.2(h)(10) and (h)(11) are independent from the other changes made in this final rule.

during the applicable petition filing period.

For the 10-year period of analysis of the final rule DHS estimates the annualized net cost savings of this rulemaking will be $2,199,374 annualized at 3 percent and 7 percent. Table 1 provides a more detailed summary of the final rule provisions and their impacts.

TABLE 1—SUMMARY OF PROVISIONS AND IMPACTS OF THE FINAL RULE

Final rule provisions	Description of final change to provisions	Estimated costs/transfers of provisions	Estimated benefits of provisions
1. Start Date Flexibility for Certain Cap-Subject H–1B Petitions.	☐ DHS is eliminating all the text currently at 8 CFR 214.2(h)(8)(iii)(A)(*4*), which relates to a limitation on the requested start date.	*Quantitative:* Petitioners— ☐ None DHS/USCIS— ☐ None *Qualitative:* Petitioners— ☐ None DHS/USCIS— ☐ None	*Quantitative:* Petitioners— ☐ None. DHS/USCIS— ☐ None. *Qualitative:* Petitioners— ☐ Reduced confusion regarding which start date they must put on an H–1B petition DHS/USCIS— ☐ None.
2. Additional Time Burden for the H–1B Registration System.	☐ Due to changes in the instructions, adding clarifying language regarding the denial or revocation of approved H–1B petitions, adding information collection elements related to the beneficiary centric registration selection process, namely the collection of passport or travel document information and related instructional language, and verifying such information before submitting a registration, this final rule will increase the burden per response by 5 minutes.	*Quantitative:* Petitioners— ☐ DHS estimates that the additional time to complete and submit the H–1B registration will cost $2,376,458 annually. ☐ Although many DHS rulemakings include monetized or unquantified familiarization costs, DHS believes the addition of passport or travel document information will have no likely consequence or add familiarization costs to existing burdens to review instructions, gather required documentation and complete and submit the request. DHS/USCIS— ☐ None *Qualitative:* Petitioners— ☐ None DHS/USCIS— ☐ None	*Quantitative:* Petitioners— ☐ None. DHS/USCIS— ☐ None. *Qualitative:* Petitioners— ☐ None. DHS/USCIS— ☐ None.
3. Beneficiary Centric Selection.	☐ Under the new rule, each unique individual who has a registration submitted on their behalf will be entered into the selection process once, regardless of the number of registrations submitted on their behalf. By selecting by a unique beneficiary, DHS will better ensure that each individual has the same chance of being selected, regardless of how many registrations were submitted on their behalf.	*Quantitative:* Petitioners— ☐ DHS estimates the total annual cost savings to petitioners will be $3,840,822 for the registrants' cost of time ☐ DHS estimates that there will be 73,501 fewer registrations due to this change, resulting in a $735,010 cost savings to petitioners based on those petitioners no longer needing to pay the $10 registration fee. DHS/USCIS— ☐ None *Qualitative:* Petitioners— While the final passport or travel document requirement could impact individuals who do not yet hold a valid passport or travel document at the time of registration, DHS has determined the described benefits of program integrity outweigh any additional burden to prospective beneficiaries. DHS/USCIS— ☐ None	*Quantitative:* Petitioners— ☐ None. DHS/USCIS— ☐ None. *Qualitative:* Petitioners/Beneficiaries— ☐ DHS believes that changing how USCIS conducts the selection process to select by unique beneficiaries instead of registrations will give each unique beneficiary an equal chance at selection and will reduce the advantage that beneficiaries with multiple registrations submitted on their behalf have over beneficiaries with a single registration submitted on their behalf. ☐ Selected beneficiaries with more than one legitimate registration would enjoy improved flexibility, and greater autonomy in selecting their employer. ☐ DHS cannot forecast with certainty a reduction in administrative burdens resulting from fewer selection rounds. However, the beneficiary centric selection process may reduce the likelihood that USCIS will need to run the selection process more than once in a fiscal year and may achieve the multiple benefits discussed by the commenters. DHS also acknowledges the comments that running multiple selection rounds can negatively affect beneficiaries who are already in the United States and may not be able to stay through multiple selection rounds, and notes that the beneficiary centric registration process may help potential beneficiaries in this manner as well. DHS/USCIS— ☐ None.

TABLE 1—SUMMARY OF PROVISIONS AND IMPACTS OF THE FINAL RULE—Continued

Final rule provisions	Description of final change to provisions	Estimated costs/transfers of provisions	Estimated benefits of provisions
4. Registrations with False Information or that are Otherwise Invalid.	☐ DHS is codifying its authority to deny or revoke a petition on the basis that the statement of facts on the underlying registration was not true and correct, or was inaccurate, fraudulent, or misrepresented a material fact. ☐ Additionally, DHS is codifying its authority to deny or revoke the approval of an H–1B petition if it determines that the fee associated with the registration is declined, not reconciled, disputed, or otherwise invalid after submission..	*Quantitative:* Petitioners— ☐ None DHS/USCIS— ☐ None *Qualitative:* Petitioners— ☐ DHS anticipates that USCIS adjudicators may issue more RFEs and NOIDs related to registrations with false information under this final rule, which will increase the burden on petitioners and adjudicators ☐ USCIS may deny or revoke the approval of any petition filed for the beneficiary based on those registrations with false information or if USCIS determines fee payment is declined, not reconciled, disputed, or otherwise invalid after submission. DHS/USCIS— ☐ DHS will need to spend time issuing RFEs and NOIDs related to registrations with false information.	*Quantitative:* Petitioners— ☐ None. DHS/USCIS— ☐ None. *Qualitative:* Petitioners— ☐ None. DHS/USCIS— ☐ The authority to deny or revoke a petition on the basis that the statement of facts on the underlying registration was not true and correct, or was inaccurate, fraudulent, or misrepresented a material fact will lead to improved program integrity for USCIS. ☐ The authority to deny or revoke due to failed or incomplete payment mitigates the incentive to submit payment only upon selection of registrations and will lead to improved program integrity for USCIS.

In addition to the impacts summarized above, and as required by OMB Circular A–4, Table 2 presents the prepared accounting statement showing the costs and benefits that will result in this final rule.[29]

TABLE 2—OMB A–4 ACCOUNTING STATEMENT

[$ millions, FY 2022]

Time period: FY 2023 through FY 2032				
Category	Primary estimate	Minimum estimate	Maximum estimate	Source citation
Benefits				
Monetized Benefits	N/A			Regulatory Impact Analysis (RIA).
Annualized quantified, but unmonetized, benefits.	N/A	N/A	N/A	RIA.
Unquantified Benefits	The purpose of this rulemaking is to improve the regulations relating to the H–1B registration selection process. Through this rule, DHS is implementing a beneficiary centric selection process for H–1B registrations. Instead of selecting by registration, U.S. Citizenship and Immigration Services (USCIS) will select registrations by unique beneficiary. Each unique beneficiary who has a registration submitted on their behalf will be entered into the selection process once, regardless of how many registrations are submitted on their behalf. If a beneficiary is selected, each registrant that submitted a registration on that beneficiary's behalf will be notified of selection and will be eligible to file a petition on that beneficiary's behalf during the applicable petition filing period. The beneficiary centric selection process for H–1B registrations will reduce the potential for gaming the process to increase chances for selection and help ensure that each beneficiary has the same chance of being selected, regardless of how many registrations are submitted on their behalf.			RIA.
Costs				
Annualized monetized costs (7%) Annualized monetized costs (3%) Annualized quantified, but unmonetized, costs.	−$2.2 −$2.2 N/A			RIA.
Qualitative (unquantified) costs	DHS expects program participants to comply with program requirements, and notes those that do not comply with program requirements could experience significant impacts due to this rule. DHS expects that the final rule prevents registrations with false information from taking a cap number for which they are ineligible. If registrants provide false information to gain an unfair advantage under the beneficiary centric selection process, DHS anticipates that USCIS adjudicators may issue more RFEs and NOIDs related to registrations with false information under this final rule, which will increase the burden on petitioners and adjudicators. USCIS may deny or revoke the approval of any petition filed for the beneficiary based on those registrations with false information.			RIA.
Transfers				
Annualized monetized transfers (7%).	N/A			
Annualized monetized transfers (3%).	N/A			
From whom to whom?				

[29] OMB, *Circular A–4* (Sept. 17, 2003), *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf* (last viewed June 1, 2021).

TABLE 2—OMB A–4 ACCOUNTING STATEMENT—Continued
[$ millions, FY 2022]

Time period: FY 2023 through FY 2032				
Category	Primary estimate	Minimum estimate	Maximum estimate	Source citation
From whom to whom?				
Miscellaneous analyses/category	*Effects*			*Source citation.*
Effects on State, local, or tribal governments.	None			RIA.
Effects on small businesses	None			RIA.
Effects on wages	None			None.
Effects on growth	The beneficiary centric selection process will likely increase fairness in the selection process, as well as enhance the integrity of the selection process overall. DHS anticipates that this change will also enhance transparency and predictability in the selection process by structurally limiting the potential for bad actors to game the system. As noted in the NPRM, DHS is aware that, under the registration-based selection process, an individual's chance of selection with a single registration is lower compared to beneficiaries who have multiple registrations submitted on their behalf and is optimistic that the new beneficiary centric selection system will increase fairness and help restore trust in the system.			None.

Background

Through this final rule, DHS is finalizing certain provisions relating to the beneficiary centric selection process for H–1B registrations, start date flexibility for certain H–1B cap-subject petitions, and integrity measures related to registration.

Costs, Transfers, and Benefits of the Final Rule

(1) Start Date Flexibility for Certain H–1B Cap-Subject Petitions

DHS is eliminating all the text currently at 8 CFR 214.2(h)(8)(iii)(A)(*4*), which relates to a limitation on the requested start date, because the current regulatory language creates confusion when the petition filing period extends beyond October 1 of the applicable fiscal year. The removal of this text will provide clarity and flexibility to employers with regard to the start date listed on H–1B cap-subject petitions, consistent with existing USCIS practice. This clarity may help petitioners by reducing confusion as to what start date they have to put on the petition.

In 2020, USCIS implemented the first electronic registration process for the FY 2021 H–1B cap. In that year, and for each subsequent fiscal year, prospective petitioners seeking to file H–1B cap-subject petitions (including for beneficiaries eligible for the advanced degree exemption) were required to first electronically register and pay the associated H–1B registration fee for each prospective beneficiary. Table 3 shows the number of cap-subject registrations received and selected by USCIS during Cap Year 2021 through FY 2023. Based on the 3-year annual average DHS estimates that 127,980 registrations are selected each year. DHS cannot estimate the number of petitioners that will benefit from this clarification to the start date on their petition because USCIS does not currently reject or deny petitions solely due to the start date not being October 1 of the applicable fiscal year.

TABLE 3—H–1B CAP-SUBJECT REGISTRATIONS RECEIVED AND SELECTED BY USCIS
[Cap Year 2021 through FY 2023]

Cap year	Total number of registrations received	Eligible registrations for beneficiaries with no other eligible registrations	Eligible registrations for beneficiaries with multiple eligible registrations	Selections
2021	274,237	241,299	28,125	124,415
2022	308,613	211,304	90,143	131,924
2023	483,927	309,241	165,180	127,600
3-Year Total	1,066,777	761,844	283,448	383,939
3-Year Average	355,592	253,948	94,483	127,980

Source: *https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations-and-fashion-models/h-1b-electronic-registration-process* (Mar. 30, 2023).

In FY 2024 there were 780,884 registrations received, which was a large increase from previous years shown in Table 4. Of those registrations, 758,994 were eligible and 350,103 were eligible registrations for beneficiaries with no other eligible registrations, and 408,891 were eligible registrations for beneficiaries with multiple eligible registrations. Table 4 shows the 4-year annual average including FY 2024. The FY 2024 data shows continued growth in eligible registrations for beneficiaries both with no other eligible registrations and those with multiple registrations. While Tables 3 and 4 suggest that growth in multiple registrations may continue in response to declining odds of random selection in the lottery, DHS cannot accurately project out what the share of future registrations will be for beneficiaries with multiple registrations nor how many registrations might ultimately be submitted for those beneficiaries. Furthermore, Table 3 shows that the number of eligible registrations for beneficiaries with no other eligible registrations has continued to grow for reasons unrelated to the growth in multiple registrations. Although past growth is not indicative of future trend, it is evident from the analysis presented in the NPRM and this Final Rule that should these trends continue, the cost savings estimated in this analysis would only grow larger, and consequently, DHS continues to use the 3-year annual (FY21 through FY23) average as the appropriate estimated

population for this final rule. While DHS considered the FY2024 data separately, we are not adjusting the RIA to include FY2024 because this most-recent registration data lacks necessary information on the verified total number of unique beneficiaries with registrations submitted on their behalf which this RIA uses to estimate impacts of the beneficiary centric selection process. DHS incorporated the FY 2024 data into this final rule once partial data became available to show the increase in the total number of registrations received since FY2023. Table 4 shows the 4-year annual average including FY 2024, this annual average is around 106,323 higher than the 3-year annual average shown in Table 3 even though the increase from FY 2023 to FY 2024 was an increase of 296,957.

TABLE 4—H–1B CAP-SUBJECT REGISTRATIONS RECEIVED AND SELECTED BY USCIS

[Cap year 2021 through Cap year 2024]

Cap year	Total number of registrations received	Eligible registrations for beneficiaries with no other eligible registrations	Eligible registrations for beneficiaries with multiple eligible registrations	Selections
2021	274,237	241,299	28,125	124,415
2022	308,613	211,304	90,143	131,924
2023	483,927	309,241	165,180	127,600
2024	780,884	350,103	408,891	188,400
Total	1,847,661	1,111,947	692,339	572,339
Average	461,915	277,987	173,085	143,085

Source: *https://www.uscis.gov/working-in-the-united-states/temporary-workers/h-1b-specialty-occupations-and-fashion-models/h-1b-electronic-registration-process* (Mar. 30, 2023).

(2) The H–1B Registration System

Through issuance of a final rule in 2019, *Registration Requirement for Petitioners Seeking To File H–1B Petitions on Behalf of Cap-Subject Aliens,*[30] DHS developed a new way to administer the H–1B cap selection process to streamline processing and provide overall cost savings to employers seeking to file H–1B cap-subject petitions. In 2020, USCIS implemented the first electronic registration process for the FY 2021 H–1B cap. In that year, and for each subsequent fiscal year, prospective petitioners seeking to file H–1B cap-subject petitions (including for beneficiaries eligible for the advanced degree exemption) were required to first electronically register and pay the associated H–1B registration fee for each prospective beneficiary. When registration is required, an H–1B cap-subject petition is not eligible for filing unless it is based on a selected registration that was properly submitted by the prospective petitioner, or their representative, for the beneficiary.

Table 3 shows the number of cap registration receipts by year, as well as the number of registrations that were selected to file Form I–129 H–1B petitions. The number of registrations has increased over the past 3 years. DHS believes that this increase is partially due to the increase in multiple companies submitting registrations for the same beneficiary. USCIS received a low of 274,237 H–1B registrations for cap year 2021, and a high of 483,927 H–1B registrations for cap year 2023.

DHS estimates the current public reporting time burden for an H–1B registration is 31 minutes (0.5167 hours), which includes the time for reviewing instructions, gathering the required information, and submitting the registration.

The number of Form G–28 submissions allows USCIS to estimate the number of H–1B registrations that an attorney or accredited representative submits and thus estimate the opportunity costs of time for an attorney or accredited representative to submit a registration. Table 5 shows the number of registrations received with and without Form G–28. USCIS received a low of 148,964 registrations with Form G–28 in cap year 2022, and a high of 207,053 registrations with Form G–28 in cap year 2023. Based on a 3-year annual average, DHS estimates the annual average receipts of registrations to be 171,330 with 48 percent of registrations submitted by an attorney or accredited representative.

TABLE 5—TOTAL FORM I–129 H–1B REGISTRATIONS WITH AND WITHOUT FORM G–28

[Cap year 2021 through Cap year 2023]

Cap year	Total number of H–1B registrations submitted without form G–28	Total number of H–1B registrations submitted with form G–28	Total of H–1B registration submitted	Percentage of H–1B registrations submitted with form G–28 (%)
2021	116,264	157,973	274,237	58
2022	159,649	148,964	308,613	48
2023	276,874	207,053	483,927	43
3-Year Total	552,787	513,990	1,066,777	48

[30] *See* ''Registration Requirement for Petitioners Seeking To File H–1B Petitions on Behalf of Cap-Subject Aliens,'' 84 FR 888 (Jan. 31, 2019).

TABLE 5—TOTAL FORM I–129 H–1B REGISTRATIONS WITH AND WITHOUT FORM G–28—Continued

[Cap year 2021 through Cap year 2023]

Cap year	Total number of H–1B registrations submitted without form G–28	Total number of H–1B registrations submitted with form G–28	Total of H–1B registration submitted	Percentage of H–1B registrations submitted with form G–28 (%)
3-Year Average	184,262	171,330	355,592	48

Source: USCIS, Office of Policy and Strategy, PRD, CLAIMS3 and ELIS databases, Mar. 30, 2023.

Of the 355,592 total average of H–1B registrations submitted, DHS estimates that an annual average of 282,091 unique beneficiaries with registrations will now see increase to the opportunity cost of time completing and submitting an H–1B registration. Of those 282,091 registrations, DHS estimated that an attorney or accredited representative submitted 48 percent of registrations and an HR representative submitted the remaining 52 percent shown in Table 5.

TABLE 6—H–1B CAP-SUBJECT REGISTRATIONS RECEIVED BY USCIS FOR UNIQUE BENEFICIARIES

[Cap year 2021 through 2023]

Cap year	Total registrations	Total number of registrations submitted for beneficiaries with multiple registrations	Total number of registrations submitted for beneficiaries with a single registration	Total number of unique beneficiaries with registrations submitted on their behalf	% of total registrations submitted for beneficiaries with a single registration
2021	274,237	34,349	239,888	253,331	87
2022	308,613	98,547	210,066	235,720	68
2023	483,927	176,444	307,483	357,222	64
3-year Total	1,066,777	309,340	757,437	846,273	71
3-year Annual Average	355,592	103,113	252,479	282,091	71

Source: USCIS Office of Performance and Quality.

In order to estimate the opportunity costs of time for completing and submitting an H–1B registration DHS assumes that a registrant will use an HR specialist, an in-house lawyer, or an outsourced lawyer to prepare an H–1B registration.[31] DHS uses the mean hourly wage of $35.13 for HR specialists to estimate the opportunity cost of the time for preparing and submitting the H–1B registration.[32] Additionally, DHS uses the mean hourly wage of $78.74 for in-house lawyers to estimate the opportunity cost of the time for preparing and submitting the H–1B registration.[33]

DHS accounts for worker benefits when estimating the total costs of compensation by calculating a benefits-to-wage multiplier using the BLS report detailing the average employer costs for employee compensation for all civilian workers in major occupational groups and industries. DHS estimates that the benefits-to-wage multiplier is 1.45 and, therefore, is able to estimate the full opportunity cost per petitioner, including employee wages and salaries and the full cost of benefits such as paid leave, insurance, retirement, etc.[34] DHS multiplied the average hourly U.S. wage rate for HR specialists and in-house lawyers by 1.45 to account for the full cost of employee benefits, for a total of $50.94 [35] per hour for an HR specialist and $114.17 [36] per hour for an in-house lawyer. DHS recognizes that a firm may choose, but is not required, to outsource the preparation of these petitions and, therefore, presents two wage rates for lawyers. To determine the full opportunity costs of time if a firm hired an outsourced lawyer, DHS multiplied the average hourly U.S. wage rate for lawyers by 2.5 [37] for a total of $196.85 [38] to approximate an hourly wage rate for

[31] USCIS limited its analysis to HR specialists, in-house lawyers, and outsourced lawyers to present estimated costs. However, USCIS understands that not all entities employ individuals with these occupations and, therefore, recognizes equivalent occupations may also prepare and file these petitions or registrations.

[32] *See* BLS, ''Occupational Employment and Wage Statistics, Occupational Employment and Wages, May 2022, 13–1071 Human Resources Specialists,'' *https://www.bls.gov/oes/2022/may/oes131071.htm* (last visited May 11, 2023).

[33] *See* BLS, ''Occupational Employment and Wage Statistics, Occupational Employment and Wages, May 2022, 23–1011 Lawyers,'' *https://www.bls.gov/oes/2022/may/oes231011.htm* (last visited May. 11, 2023).

[34] The benefits-to-wage multiplier is calculated as follows: (Total Employee Compensation per hour)/(Wages and Salaries per hour) ($42.48 Total Employee Compensation per hour)/($29.32 Wages and Salaries per hour) = 1.44884 = 1.45 (rounded). *See* BLS, Economic News Release, ''Employer Costs for Employee Compensation'' (Dec. 2022), Table 1. ''Employer Costs for Employee Compensation by ownership'' (Dec. 2022), *https://www.bls.gov/news.release/archives/ecec_03172023.htm* (last visited Mar. 21, 2023). The Employer Costs for Employee Compensation measures the average cost to employers for wages and salaries and benefits per employee hour worked.

[35] Calculation: $35.13 * 1.45 = $50.94 total wage rate for HR specialist.

[36] Calculation: $78.74 * 1.45 = $114.17 total wage rate for in-house lawyer.

[37] DHS Immigration and Customs Enforcement (ICE), ''Safe-Harbor Procedures for Employers Who Receive a No-Match Letter,'' used a multiplier of 2.5 to convert in-house attorney wages to the cost of outsourced attorney based on information received in public comment to that rule. We believe the explanation and methodology used in the Final Small Entity Impact Analysis for that rule remains sound for using 2.5 as a multiplier for outsourced labor wages in this final rule, *see https://www.regulations.gov/document/ICEB-2006-0004-0922,* at page G–4.

[38] Calculation: $78.74 * 2.5 = $196.85 total wage rate for an outsourced lawyer.

an outsourced lawyer [39] to prepare and submit an H–1B registration.[40]

Table 7 displays the estimated annual opportunity cost of time for submitting an H–1B registration employing an in-house or outsourced lawyer to complete and submit an H–1B registration. DHS does not know the exact number of registrants who will choose an in-house or an outsourced lawyer but assumes it may be a 50/50 split and therefore provides an average. These current opportunity costs of time for submitting an H–1B registration using an attorney or other representative are estimated to range from $7,987,704 to $13,772,265 with an average of $10,879,985.

TABLE 7—CURRENT AVERAGE OPPORTUNITY COSTS OF TIME FOR SUBMITTING AN H–1B REGISTRATION WITH AN ATTORNEY OR OTHER REPRESENTATIVE

	Population submitting with a lawyer A	Time burden to complete H–1B registration (hours) B	Cost of time C	Total current opportunity cost D = (A × B × C)
In-house lawyer	135,404	0.5167	$114.17	$7,987,704
Outsourced lawyer	135,404	0.5167	196.85	13,772,265
Average				10,879,985

Source: USCIS Analysis.

To estimate the current remaining opportunity cost of time for an HR specialist submitting an H–1B registration without a lawyer, DHS applies the estimated public reporting time burden (0.5167 hours) to the compensation rate of an HR specialist. Table 8 estimates the current total annual opportunity cost of time to HR specialists completing and submitting an H–1B registration will be approximately $3,860,904.

TABLE 8—CURRENT AVERAGE OPPORTUNITY COSTS OF TIME FOR SUBMITTING AN H–1B REGISTRATION, WITHOUT AN ATTORNEY OR ACCREDITED REPRESENTATIVE

	Population A	Time burden to complete H–1B registration (hours) B	HR specialist's opportunity cost of time C	Total opportunity cost of time D = (A × B × C)
Estimate of H–1B Registrations	146,687	0.5167	$50.94	$3,860,904

Source: USCIS Analysis.

Table 9 shows the final estimated time burden will increase by 5 minutes to 36 minutes (0.6 hours) to the eligible population and compensation rates of those who may submit registrations with or without a lawyer due to changes in the instructions, adding clarifying language regarding denying or revoking approved H–1B petitions, adding passport or travel document instructional language, and verifying such information before submitting registrations. DHS does not know the exact number of registrants who will choose an in-house or an outsourced lawyer but assumes it may be a 50/50 split and therefore provides an average. DHS estimates that these current opportunity costs of time for submitting an H–1B registration using an attorney or other representative range from $9,275,445 to $15,992,566 with an average of $12,634,006.

[39] The DHS analysis in ''Exercise of Time-Limited Authority To Increase the Fiscal Year 2018 Numerical Limitation for the H–2B Temporary Nonagricultural Worker Program,'' 83 FR 24905 (May 31, 2018), *https://www.federalregister.gov/documents/2018/05/31/2018-11732/exercise-of-time-limited-authority-to-increase-the-fiscal-year-2018-numerical-limitation-for-the,* used a multiplier of 2.5 to convert in-house attorney wages to the cost of outsourced attorney wages. The ICE rule ''Final Small Entity Impact Analysis: 'Safe-Harbor Procedures for Employers Who Receive a No-Match Letter' '' at G–4 (Aug. 25, 2008), *https://www.regulations.gov/document/ICEB-2006-0004-0922,* also uses a multiplier. The methodology used in the Final Small Entity Impact Analysis remains sound for using 2.5 as a multiplier for outsourced labor wages in this final rule.

[40] The DHS analysis in ''Exercise of Time-Limited Authority To Increase the Fiscal Year 2018 Numerical Limitation for the H–2B Temporary Nonagricultural Worker Program,'' 83 FR 24905 (May 31, 2018), *https://www.federalregister.gov/documents/2018/05/31/2018-11732/exercise-of-time-limited-authority-to-increase-the-fiscal-year-2018-numerical-limitation-for-the,* used a multiplier of 2.5 to convert in-house attorney wages to the cost of outsourced attorney wages. Also, the analysis for a DHS ICE rule, ''Final Small Entity Impact Analysis: 'Safe-Harbor Procedures for Employers Who Receive a No-Match Letter' '' at G–4 (Aug. 25, 2008), *https://www.regulations.gov/document/ICEB-2006-0004-0922,* used a multiplier. The methodology used in the Final Small Entity Impact Analysis remains sound for using 2.5 as a multiplier for outsourced labor wages in this final rule.

TABLE 9—NEW OPPORTUNITY COSTS OF TIME FOR AN H–1B REGISTRATION, REGISTRANTS SUBMITTING WITH AN ATTORNEY OR OTHER REPRESENTATIVE

	Population of registrants submitting with a lawyer A	Time burden to complete H–1B registration (hours) B	Cost of time C	Total opportunity cost D = (A × B × C)
In House Lawyer	135,404	0.6	$114.17	$9,275,445
Outsourced Lawyer	135,404	0.6	$196.85	15,992,566
Average				12,634,006

Source: USCIS Analysis.

To estimate the current remaining opportunity cost of time for an HR specialist submitting an H–1B registration without a lawyer, DHS applies the final estimated public reporting time burden (0.6 hours) to the compensation rate of an HR specialist. Table 10 estimates the current total annual opportunity cost of time to HR specialists completing and submitting the H–1B registration will be approximately $4,483,341.

TABLE 10—FINAL AVERAGE OPPORTUNITY COSTS OF TIME FOR AN H–1B REGISTRATION, SUBMITTING WITHOUT AN ATTORNEY OR ACCREDITED REPRESENTATIVE

	Population A	Time burden to complete H–1B registration (hours) B	HR specialist's opportunity cost of time (48.40/hr.) C	Total opportunity cost of time D = (A × B × C)
Estimate H–1B Registration	146,687	0.6	$50.94	$4,483,341

Source: USCIS Analysis.

DHS estimates the total additional annual cost for attorneys and HR specialists to complete and submit H–1B registrations are expected to be $2,376,458 shown in Table 11. This table shows the current total opportunity cost of time to submit an H–1B registration and the final total opportunity cost of time.

TABLE 11—TOTAL COSTS TO COMPLETE THE H–1B REGISTRATION

Average Current Opportunity Cost Time for Lawyers to Complete the H–1B Registration	$10,879,985
Average Current Opportunity Cost Time for HR Specialist to Complete the H–1B Registration	3,860,904
Total	14,740,889
Average Final Opportunity Cost Time for Lawyers to Complete the H–1B Registration	12,634,006
Average Final Opportunity Cost Time for HR Specialist to Complete the H–1B Registration	4,483,341
Total	17,117,347
Final Additional Opportunity Costs of Time to Complete the H–1B Registration	2,376,458

Source: USCIS Analysis.

(3) Beneficiary Centric Selection

Under the final provision, DHS will modify the random selection process. Registrants will continue to submit registrations on behalf of beneficiaries, and beneficiaries will continue to be able to have more than one registration submitted on their behalf, as generally allowed by applicable regulations. If a random selection were necessary (meaning, more registrations are submitted than the number of registrations USCIS projected as needed to reach the numerical allocations), then the random selection will be based on each unique beneficiary identified in the registration pool, rather than each registration. If a beneficiary is selected, then all registrants who properly submitted a registration for that selected beneficiary will be notified of the selection and that they are eligible to file an H–1B cap petition on behalf of the beneficiary during the applicable petition filing period.

DHS believes that changing how USCIS conducts the selection process to select by unique beneficiaries instead of registrations will give each unique beneficiary an equal chance at selection and will reduce the advantage that beneficiaries with multiple registrations submitted on their behalf have over beneficiaries with a single registration submitted on their behalf. DHS believes that it will also reduce the incentive that registrants may have to work with others to submit registrations for the same beneficiary to unfairly increase the chance of selection for the beneficiary because doing so under the beneficiary centric selection approach will not result in an increase in the odds of selection. Selecting by unique beneficiary could also result in other benefits, such as giving beneficiaries greater autonomy regarding their H–1B employment. Under the baseline, employers attest that the registration reflects a legitimate job offer and they did not work with others to improve their chance of selection, and some beneficiaries have multiple legitimate registrations. Some beneficiaries who registered multiple times may see their relative odds of at least one lottery selection decline as a result of this rule, but this effect will be offset by the increased autonomy for beneficiaries. Under the current registration based selection process, beneficiaries with multiple registrations have their offer of employment determined by which registrant (prospective employer) was selected. After this final rule is in effect, selecting by unique beneficiary and providing each registrant with a selection notice will allow beneficiaries to select from among the registrants with legitimate job offers thus potentially giving beneficiaries greater autonomy regarding their H–1B employment; these beneficiaries may also have greater bargaining power or flexibility to negotiate with prospective employers.

The integrity of the new selection process will rely on USCIS's ability to accurately identify each individual beneficiary, and all registrations submitted on their behalf. DHS is requiring the submission of valid passport information or valid travel document information, including the passport or travel document number, country of issuance, and expiration date, in addition to the currently required information. *See* new 8 CFR 214.2(h)(8)(iii)(A)(*4*)(*ii*). While the final passport or travel document requirement could impact individuals who do not yet hold valid passports or travel documents at the time of registration, DHS has determined the described benefits of program integrity outweigh any additional burden to prospective beneficiaries.

DHS estimates that the annual average receipts of H–1B registrations is 355,592 with 71 percent of registrations being submitted for a beneficiary with only a single registration. DHS estimates that 29 percent [41] of registrations are submitted by companies for beneficiaries who have also had other registrations submitted on their behalf. Based on this new provision, DHS estimates that there may be a reduction in registrations because beneficiaries will be less inclined to find as many different employers to submit registrations on their behalf as doing so will not affect their chance of selection. Also, DHS expects to see less abuse by unscrupulous registrants as they will not be able to increase the chance of selection for a beneficiary by working together with others to submit multiple registrations for the same beneficiary.

TABLE 12—H–1B CAP-SUBJECT REGISTRATIONS RECEIVED BY USCIS FOR UNIQUE BENEFICIARIES

[Cap Year 2021 Through 2023]

Cap year	Total registrations	Total number of registrations submitted for beneficiaries with multiple registrations	Total number of registrations submitted for beneficiaries with a single registration	Total number of unique beneficiaries with registrations submitted on their behalf	% of total registrations submitted for beneficiaries with a single registration (%)
2021	274,237	34,349	239,888	253,331	87
2022	308,613	98,547	210,066	235,720	68
2023	483,927	176,444	307,483	357,222	64
3-year Total	1,066,777	309,340	757,437	846,273	71
3-year Annual Average	355,592	103,113	252,479	282,091	71

Source: USCIS Office of Performance and Quality.

DHS estimates that 73,501 [42] registrations annually may no longer be submitted due to this final rule change. Of those 73,501 registrations, DHS estimated that an attorney or accredited representative submitted 48 percent of registrations and an HR representative submitted the remaining 52 percent shown in Table 5.

Table 13 displays the estimated annual opportunity cost of time for submitting an H–1B registration employing an in-house or outsourced lawyer to complete and submit an H–1B

[41] Calculation: 100% − 71% Registrations for a single beneficiary = 29% Registrations submitted for multiple beneficiaries.

[42] Calculation: Total Registrations 355,592 − Total average number of unique beneficiaries with registrations submitted on their behalf 282,091 = 73,501 Estimate of registrations that may no longer be submitted.

registration. DHS does not know the exact number of prospective petitioners who will choose an in-house or an outsourced lawyer but assumes it may be a 50/50 split and therefore provides an average. DHS estimates that these current opportunity costs of time for submitting an H–1B registration using an attorney or other representative range from $2,081,225 to $3,588,413, with an average of $2,834,819.

TABLE 13—CURRENT ANNUAL AVERAGE OPPORTUNITY COSTS OF TIME FOR SUBMITTING AN H–1B REGISTRATION, WITH AN ATTORNEY OR OTHER REPRESENTATIVE

	Population of registrants submitting with a lawyer A	Time burden to complete H–1B registration (hours) B	Cost of time C	Total current opportunity cost D = (A × B × C)
In House Lawyer	35,280	0.5167	$114.17	$2,081,225
Outsourced Lawyer	35,280	0.5167	196.85	3,588,413
Average				2,834,819

Source: USCIS Analysis.

To estimate the current remaining opportunity cost of time for an HR specialist submitting an H–1B registration without a lawyer, DHS applies the estimated public reporting time burden (0.5167 hours) to the compensation rate of an HR specialist. Table 14 estimates the current total annual opportunity cost of time to HR specialists completing and submitting an H–1B registration will be approximately $1,006,003.

TABLE 14—CURRENT ANNUAL AVERAGE OPPORTUNITY COSTS OF TIME FOR SUBMITTING AN H–1B REGISTRATION, WITHOUT AN ATTORNEY OR ACCREDITED REPRESENTATIVE

	Population A	Time burden to complete H–1B registration (hours) B	HR specialist's opportunity cost of time C	Total opportunity cost of time D = (A × B × C)
Estimate of H–1B Registrations	38,221	0.5167	$50.94	$1,006,003

Source: USCIS Analysis.

DHS estimates the total annual opportunity cost savings of time for not having to complete and submit H–1B registrations for beneficiaries with multiple registrations are expected to be $3,840,822, shown in Table 15.

TABLE 15—TOTAL ANNUAL OPPORTUNITY COST SAVINGS OF TIME FOR H–1B REGISTRATIONS

Average Current Opportunity Cost Time for Lawyers to Complete H–1B Registration	$2,834,819
Average Current Opportunity Cost Time for HR Specialist to Complete H–1B Registration	1,006,003
Total	3,840,822

Source: USCIS Analysis.

Prospective petitioners seeking to file H–1B cap-subject petitions, including for beneficiaries eligible for the additional visas for advanced degree holders, must first electronically register and pay the associated $10 H–1B registration fee for each prospective beneficiary. Due to this final change DHS estimates that prospective petitioners may now see an additional cost savings of $735,010. The annual total cost savings of this final beneficiary centric selection is $4,575,832.[43]

TABLE 16—TOTAL ANNUAL COST SAVINGS FOR REGISTRATION FEES

Annual Registrations for the same beneficiaries	73,501
Registration Fee	$10
Total Cost savings	$735,010

Source: USCIS Analysis.

For purposes of this regulatory impact analysis, summarized in Table 2 A–4 Accounting Statement, the existing $10 registration fee is the appropriate baseline against which the impacts of the rule should be evaluated, however, DHS is simultaneously working on finalizing the ''U.S. Citizenship and Immigration Services Fee Schedule and Changes to Certain Other Immigration Benefit Request Requirements'' Rule. In the NPRM, USCIS proposed to increase the H–1B registration fee from $10 to $215. If DHS were to finalize the proposed increase, Table 16b shows an even larger cost savings to registrants based on the estimated reduction in the number of registrations that would be submitted. Currently the cost savings would be $735,010 shown in Table 6 but would increase to $15,802,715 in Table 16b. If USCIS continued to see increased numbers of annual registrations for beneficiaries with multiple registrations, then the total cost savings of this rule would increase, for example if USCIS saw 100,000 annual registrations for beneficiaries with multiple registrations when the registration fee is $215, DHS would see a $21,500,000[44] cost savings from the beneficiary centric selection.

[43] Calculation: Total Opportunity Cost Savings of time for H–1B Registrations ($3,840,822) + Total Cost Savings for Registration Fees ($735,010) = $4,575,832 Total Cost Savings.

[44] Calculation: 100,000 Annual Registrations for beneficiaries with multiple registrations × $215 Registration Fee = $21,500,000 Cost savings.

TABLE 16b—TOTAL ANNUAL COST SAVINGS FOR REGISTRATION FEES

Annual Registrations for beneficiaries with multiple registrations	73,501
Registration Fee	$215
Total Cost savings	$15,802,715

Source: USCIS Analysis.

(4) Registrations With False Information or That Are Otherwise Invalid

Although registration is an antecedent procedural step undertaken prior to filing an H–1B petition, the validity of the registration information is key to the registrant's eligibility to file a petition. As stated in the current regulations, ''[t]o be eligible to file a petition for a beneficiary who may be counted against the H–1B regular cap or the H–1B advanced degree exemption for a particular fiscal year, a registration must be properly submitted in accordance with 8 CFR 103.2(a)(1), [8 CFR 214.2(h)(8)(iii),] and the form instructions.'' *See* 8 CFR 214.2(h)(8)(iii)(A)(*1*). USCIS does not consider a registration to be properly submitted if the information contained in the registration, including the required attestations, was not true and correct. Currently, the regulations state that it is grounds for denial or revocation if the statements of facts contained in the petition are not true and correct, inaccurate, fraudulent, or misrepresented a material fact. DHS will clarify in the regulations that the grounds for denial of an H–1B petition or revocation of an H–1B petition approval extend to the information provided in the registration and to expressly state in the regulations that this includes attestations on the registration that are determined by USCIS to be false.

DHS is also changing the regulations governing registration to provide USCIS with clearer authority to deny or revoke the approval of a petition based on a registration that was not properly submitted or was otherwise invalid.

Specifically, DHS is adding that if a petitioner submits more than one registration per beneficiary in the same fiscal year, all registrations filed by that petitioner relating to that beneficiary for that fiscal year may be considered not only invalid, but that ''USCIS may deny or revoke the approval of any petition filed for the beneficiary based on those registrations.''

Additionally, DHS is adding that USCIS may deny or revoke the approval of an H–1B petition if it determines that the fee associated with the registration is declined, not reconciled, disputed, or otherwise invalid after submission.

These final changes may increase the need for RFEs and NOIDs. It is important to note that issuing RFEs and NOIDs takes time and effort for adjudicators—to send, receive, and adjudicate documentation—and it requires additional time and effort for petitioners to respond, resulting in extended timelines for adjudications.[45] Data on RFEs and NOIDs related to H–1B false information are not standardized or tracked in a consistent way, thus they are not accurate or reliable.

(5) Alternatives Considered

DHS considered the alternative of eliminating the registration system and reverting to the paper-based filing system stakeholders used prior to implementing registration. However, when DHS considered the cost savings that registration provides to both USCIS and stakeholders and the significant resources the agency would incur to revert back to a paper-based H–1B cap selection process, the benefits of having a registration system still outweigh the costs of abuse of the system.

Total Quantified Net Costs of the Final Regulatory Changes

In this section, DHS presents the total annual cost savings of this final rule annualized over a 10-year period of analysis. Table 17 details the annual cost savings of this final rule. DHS estimates the total cost savings is $4,575,832. This cost savings is based on the current registration fee of $10 per registration.

[45] The regulations state that when an RFE is served by mail, the response is timely filed if it is received no more than 3 days after the deadline, providing a total of 87 days for a response to be submitted if USCIS provides the maximum period of 84 days under the regulations. The maximum response time for a NOID is 30 days. *See* Citizenship and Immigr. Servs., U.S. Dep't of Homeland Security, USCIS Policy Manual, Volume 1, ''General Policies and Procedures,'' Part E, ''Adjudications'', Chapter 6, ''Evidence.'' *https://www.uscis.gov/policy-manual/volume-1-part-e-chapter-6.*

TABLE 17—SUMMARY OF COST SAVINGS

Description	Cost savings
Beneficiary Centric Selection Cost of Time	$3,840,822
Beneficiary Centric Selection Cost of Registrations	735,010
Total Cost Savings	4,575,832

Source: USCIS Analysis.

Table 17b shows the annual cost savings of this final rule under the proposed $215 registration fee. DHS estimates the total cost savings would be $19,643,537. The estimates in Tables 16b and 17b serve only to illustrate the impact to cost savings estimates if the fee is increased to $215 in a separate rulemaking.[46]

TABLE 17b—SUMMARY OF COST SAVINGS—UNDER PROPOSED REGISTRATION FEE INCREASE

Description	Cost savings
Beneficiary Centric Selection Cost of Time	$3,840,822
Beneficiary Centric Selection Cost of Registrations (Proposed $215 Fee)	15,802,715
Total Cost Savings	19,643,537

Source: USCIS Analysis.

DHS summarizes the annual costs of this final rule. Table 18 details the annual costs of this final rule. DHS estimates the total cost is $2,376,458.

TABLE 18—SUMMARY OF COSTS

Description	Costs
The H–1B Registration System	$2,376,458
Total Costs	2,376,458

Source: USCIS Analysis.

Net cost savings to the public of $2,199,374 are the total costs minus cost savings.[47] Table 19 illustrates that over a 10-year period of analysis from FY 2023 through FY 2032 annualized cost savings will be $2,199,374 using 7-percent and 3-percent discount rates.

[46] *See* ''U.S. Citizenship and Immigration Services Fee Schedule and Changes to Certain Other Immigration Benefit Request Requirements,'' 88 FR 402, 527 (Jan. 4, 2023) (proposed rule).

[47] Calculations: $4,575,832 Total Cost Savings – $2,376,458 Total Costs = $2,199,3741 Net Cost Savings.

TABLE 19—DISCOUNTED NET COST SAVINGS OVER A 10-YEAR PERIOD OF ANALYSIS

Fiscal year	Total estimated cost savings	
	$2,199,374 (Undiscounted)	
	Discounted at 3 percent	Discounted at 7 percent
2023	$2,135,315	$2,055,490
2024	2,073,121	1,921,018
2025	2,012,739	1,795,344
2026	1,954,115	1,677,892
2027	1,897,199	1,568,123
2028	1,841,941	1,465,536
2029	1,788,292	1,369,660
2030	1,736,206	1,280,056
2031	1,685,637	1,196,314
2032	1,636,541	1,118,050
10-year Total	18,761,106	15,447,483
Annualized Cost	2,199,374	2,199,374

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601 and 602, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, requires Federal agencies to consider the potential impact of regulations on small businesses, small governmental jurisdictions, and small organizations during the development of their rules. 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.[48]

An ''individual'' is not considered a small entity and costs to an individual are not considered a small entity impact for RFA purposes. In addition, the courts have held that the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates small entities.[49] Consequently, indirect impacts from a rule on a small entity are not considered as costs for RFA purposes.

USCIS's RFA analysis for this final rule focuses on the population of Form I–129 petitions for H–1B workers as a proxy for the impacts of this rule focused on H–1B registrations and associated registrants. Since H–1B registration is an antecedent procedural step taken before a selected registrant can file an H–1B petition, this is an appropriate proxy for analyzing the impacts of this final rule action on small entities. Where cost savings occur from multiple registrants no longer registering on behalf of a common beneficiary, either deliberately or inadvertently, USCIS is unable to quantify the portion of potential cost savings accruing to small entities. Some of these cost savings may be partially offset by the advantage multiple registrations conferred over single, unique registrants, but it is ambiguous whether such small entities enjoy this advantage or feel increasingly compelled to do this by their belief that other registrants are doing so.

1. A statement of the need for, and objectives of, the rule.

The purpose of this rulemaking is to amend the regulations relating to the H–1B registration selection process.

2. A statement of the significant issues raised by the public comments in response to the IRFA, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

DHS invited comments in the NPRM but did not receive any comments specific to the IRFA.[50] USCIS responded to general comments concerning the rule in Section III. Public Comments on the Proposed Rule.

3. The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.

[48] A small business is defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act, 15 U.S.C. 632.

[49] *See* Small Business Administration, ''A Guide For Government Agencies, How to Comply with the Regulatory Flexibility Act,'' at 22, *https://advocacy.sba.gov/wp-content/uploads/2019/06/How-to-Comply-with-the-RFA.pdf* (last visited Aug. 23 2023).

[50] Note however, that in ''U.S. Citizenship and Immigration Services Fee Schedule and Changes to Certain Other Immigration Benefit Request Requirements,'' 88 FR 402, 527 (Jan. 4, 2023) (proposed rule), DHS proposed to increase the H–1B registration fee from $10 to $215 per registration submitted. While the underlying purpose of the proposed fee increase is to ensure full cost recovery for USCIS adjudication and naturalization services, DHS recognizes the possibility that the increase in the H–1B registration fee may have an impact on the number of H–1B registrations submitted, including those submitted to improperly increase the chance of selection. However, any potential impact of that separate regulatory proposal is purely speculative. DHS also acknowledged this related rulemaking in the NPRM. *See* 88 FR 72870, 72897 (Oct. 23, 2023).

DHS invited comments in NPRM but did not receive any comments filed by the Chief Counsel for Advocacy of the Small Business Administration.

4. A description and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available.

For this analysis, DHS conducted a sample analysis of historical Form I–129 H–1B petitions to estimate the number of small entities impacted by this rule. DHS utilized a subscription-based electronic database of U.S. entities, ReferenceUSA, as well as three other open-access, free databases of public and private entities, Manta, Cortera, and Guidestar to determine the North American Industry Classification System (NAICS) code, revenue, and employee count for each entity. To determine whether an entity is small for purposes of RFA, DHS first classified the entity by its NAICS code and then used Small Business Administration (SBA) guidelines to classify the revenue or employee count threshold for each entity. Some entities were classified as small based on their annual revenue, and some by their numbers of employees.

Using FY 2022 internal data on actual filings of Form I–129 H–1B petitions, DHS identified 44,593 unique entities. DHS devised a methodology to conduct the small entity analysis based on a representative, random sample of the potentially impacted population. DHS first determined the minimum sample size necessary to achieve a 95-percent confidence level confidence interval estimation for the impacted population of entities using the standard statistical formula at a 5-percent margin of error. DHS then created a sample size greater than the minimum necessary to increase the likelihood that our matches would meet or exceed the minimum required sample. DHS notes that the random sample was drawn from the population of Form I–129 H–1B petitioners for purposes of estimating impacts of each provision in the NPRM, including those finalized here, on the population of Form I–129 H–1B petitioners at-large. Alternative approaches would be to draw a random sample from the population of H–1B registrants, however, this approach encounters the same problem this final rule seeks to address. Namely, it is difficult to discern the relationship between registrations and the Form I–129 H–1B administrative data. Thus, analyzing the impact of changes to registrations by unique entities using a sample of Form I–129 H–1B data is preferred.

DHS randomly selected a sample of 3,396 entities from the population of 44,593 entities that filed Form I–129 for H–1B petitions in FY 2022. Of the 3,396 entities, 1,724 entities returned a successful match of a filing entity in the ReferenceUSA, Manta, Cortera, and Guidestar databases; 1,672 entities did not return a match. Using these databases' revenue or employee count and their assigned NAICS code, DHS determined 1,209 of the 1,724 matches to be small entities, 515 to be non-small entities. DHS assumes filing entities without database matches or missing revenue/employee count data are likely to be small entities. As a result, in order to prevent underestimating the number of small entities this final rule will affect, DHS considers all the non-matched and missing entities as small entities for the purpose of this analysis. Therefore, DHS classifies 2,881 of 3,396 entities as small entities, including combined non-matches (1,672), and small entity matches (1,209). Thus, DHS estimates that 84.8 percent (2,881 of 3,396) of the entities filing Form I–129 H–1B petitions are small entities.

In this analysis DHS assumes that the distribution of firm size for our sample is the same as the entire population of Form I–129 H–1B petitioners. Thus, DHS estimates the number of small entities to be 84.8 percent of the population of 44,593 entities that filed Form I–129 under the H–1B classification, as summarized in Table 19 below. The annual numeric estimate of the small entities impacted by this final rule is 37,815 entities.[51]

TABLE 19—NUMBER OF SMALL ENTITIES FOR FORM I–129 FOR H–1B, FY 2022

Population	Number of small entities	Proportion of population (percent)
44,593	37,815	84.8

Following the distributional assumptions above, DHS uses the set of 1,209 small entities with matched revenue data to estimate the economic impact of the final rule on each small entity. Typically, DHS will estimate the economic impact, in percentage, for each small entity is the sum of the impacts of the final changes divided by the entity's sales revenue.[52] DHS constructed the distribution of economic impact of the final rule based on the 1,209 small entity matches in the sample. Because this final rule resulted in an overall cost savings for registrants there also would be no adverse impact on the estimated small entity population. Based on FY 2022 revenue, of the 1,209 small entities, 0 percent (0 small entities) would experience a cost increase that is greater than 1 percent of revenues.

5. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the types of professional skills necessary for preparation of the report or record.

The beneficiary centric selection process would result in additional burden to employers reporting beneficiaries' passport or travel document information in the registration system. DHS estimates increase for each of these respective burdens is 5 minutes.

6. A description of the steps the agency has taken to minimize the significant adverse economic impact on small entities

With respect to beneficiary centric selection process, there are no burdens to be minimized. While collection of passport or travel document information imposes some burden to prospective employers, USCIS found no other alternatives that achieved stated objectives with less burden to small entities.

[51] The annual numeric estimate of the small entities (37,815) = Population (44,593) * Percentage of small entities (84.8%).

[52] The economic impact, in percentage, for each small entity *i* = ((Cost of one petition for entity *i* × Number of petitions for entity *i*)/Entity *i*'s sales revenue) × 100.

The cost of one petition for entity *i* ($1 − 4.43) is estimated by dividing the total cost of this proposed rule by the estimated population. −$2,199,374/355,592 = −$6.19

The entity's sales revenue is taken from ReferenceUSA, Manta, Cortera, and Guidestar databases.

C. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and Tribal governments. Title II of UMRA requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed rule, or final rule for which the agency published a proposed rule, that includes any Federal mandate that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector.[53]

In addition, the inflation-adjusted value of $100 million in 1995 is approximately $192 million in 2022 based on the Consumer Price Index for All Urban Consumers (CPI–U).[54] This final rule does not contain a Federal mandate as the term is defined under UMRA.[55] The requirements of title II of UMRA, therefore, do not apply, and DHS has not prepared a statement under UMRA.

D. Congressional Review Act

OIRA has determined that this final rule is not a major rule, as defined in 5 U.S.C. 804, for purposes of Congressional review of agency rulemaking pursuant to the Congressional Review Act, Public Law 104–121, title II, sec. 251 (Mar. 29, 1996), 110 Stat. 868 (codified at 5 U.S.C. 801–808). This rule will not result in an annual effect on the economy of $100 million or more.

DHS will send this rule to Congress and to the Comptroller General as required by 5 U.S.C. 801(a)(1).

E. Executive Order 13132 (Federalism)

This final rule would 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. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988: Civil Justice Reform

This final rule was drafted and reviewed in accordance with E.O. 12988, Civil Justice Reform. This final rule was written to provide a clear legal standard for affected conduct and was carefully reviewed to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. DHS has determined that this final rule meets the applicable standards provided in section 3 of E.O. 12988.

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

This final rule does not have ''tribal implications'' because it will not have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, E.O. 13175, Consultation and Coordination with Indian Tribal Governments, requires no further agency action or analysis.

H. National Environmental Policy Act (NEPA)

National Environmental Policy Act Public Comments

As discussed in the NEPA section of the NPRM,[56] DHS proposed a broader set of reforms in the H–1B program, as well as discrete reforms impacting other nonimmigrant programs. DHS received one public comment on the NEPA discussion in the NPRM. DHS is addressing that comment here to the extent it pertains to the provisions of this final rule. DHS will also consider the public comment in the context of any future rule it may issue to finalize the remainder of the reforms proposed in the NPRM.

Comment: One commenter asserted that DHS's reliance on categorical exclusion (''CATEX'') A3 [57] is arbitrary and capricious and indicated that DHS must prepare an environmental impact statement or at least an environmental assessment before finalizing the NPRM. The commenter asserted that the action proposed in the NPRM is an action that, by its nature, increases the population because its goal is to increase the number of foreign nationals who enter the country. The commenter argued that the action proposed in the NPRM has the potential to have a cumulative effect when combined with other actions that increase levels of immigration, and that it should be considered rather than categorically excluded. The commenter further stated that DHS's use of categorical exclusion A3 is ''entirely irrational'' because DHS could not assess the environmental impact of the rule and thus concluded that the rule is of the type that would not have any. The commenter further stated that the NPRM does not fit into any of the categories under CATEX A3, and that DHS was not considering rules that increase immigration to the United States when it formulated this rule.

Response: DHS disagrees with both the factual and the legal assertions made by this commenter. The commenter cited no data, analysis, evidence, or statements made by DHS in the NPRM to support the commenter's assertion. Specifically with respect to the provisions being finalized through this rule, the intended and expected impact of those provisions has no relationship to increasing the number of foreign nationals in the United States. Rather, as discussed throughout this preamble, DHS is amending existing regulations to make the H–1B registration selection process fairer for all beneficiaries and improve the integrity of the program as a whole. The inclusion of start date flexibility in this final rule eliminates a confusing regulatory provision and aligns with current USCIS practice to allow petitioners to list a start date on the H–1B petition that is later than October 1 of a fiscal year for which an H–1B registration was selected. In addition, the expansion of existing regulatory provisions governing the denial of H–1B, H–2A, and H–2B petitions based on false statements

[53] *See* 2 U.S.C. 1532(a).

[54] *See* BLS, ''Historical Consumer Price Index for All Urban Consumers (CPI–U): U.S. city average, all items, by month,'' *www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202212.pdf* (last visited Jan. 19, 2023). Calculation of inflation: (1) Calculate the average monthly CPI–U for the reference year (1995) and the current year (2022); (2) Subtract reference year CPI–U from current year CPI–U; (3) Divide the difference of the reference year CPI–U and current year CPI–U by the reference year CPI–U; (4) Multiply by 100 = [(Average monthly CPI–U for 2022 − Average monthly CPI–U for 1995)/(Average monthly CPI–U for 1995)] * 100 = [(292.655 − 152.383)/152.383] * 100 = (140.272/152.383) * 100 = 0.92052263 * 100 = 92.05 percent = 92 percent (rounded). Calculation of inflation-adjusted value: $100 million in 1995 dollars * 1.92 = $192 million in 2022 dollars.

[55] The term ''Federal mandate'' means a Federal intergovernmental mandate or a Federal private sector mandate. *See* 2 U.S.C. 1502(1), 658(6).

[56] 88 FR 72870, 72955 (Oct. 23, 2023).

[57] The commenter stated: ''Categorical exclusion A3, in full, is as follows: A3 Promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, advisory circulars, and other guidance documents of the following nature: (a) Those of a strictly administrative or procedural nature; (b) Those that implement, without substantive change, statutory or regulatory requirements; (c) Those that implement, without substantive change, procedures, manuals, and other guidance documents; (d) Those that interpret or amend an existing regulation without changing its environmental effect; (e) Technical guidance on safety and security matters; or (f) Guidance for the preparation of security plans.''

(including findings of fraud or willful misrepresentation) made not only in the petition, but also in the H–1B registration, LCA, or TLC, as applicable, is intended to improve program integrity and provide USCIS with more explicit authority to deny or revoke petitions on the basis of false statements (including findings of fraud or willful misrepresentation). The amendments to existing regulations in this final rule clearly fit within CATEX A3 because they are administrative in nature, do not have the potential for significantly affecting the environment, and do not result in a change in any environmental effect of the current regulations. For example, the current H–1B registration process is fully electronic—registrants submit electronic registrations into the system and DHS selects from those registrations toward the 65,000 statutory annual cap or the statutory 20,000 advanced degree exemption. After implementation of this final rule, DHS will continue to select toward the two statutory allocations but will do so based on each unique beneficiary, rather than registration. This change is not intended to increase the number of visas or foreign nationals that may come to the United States, and DHS does not foresee such an increase given the statutorily mandated annual numerical limitations. With respect to the start date flexibility provisions, DHS already accepts H–1B petitions with start dates after October 1 of a fiscal year so long as the start date is in the same fiscal year as the fiscal year for which an H–1B registration is selected and within 6 months of the petition filing date. This regulatory change is not intended to increase the number of visas or foreign nationals in the United States, and DHS does not foresee such an increase because start date flexibility is merely a technical change to eliminate potential confusion when the applicable filing period extends after October 1 of the applicable fiscal year. Finally, the provisions governing the denial and revocation of petitions will provide more explicit authority for USCIS to deny or revoke H–1B petitions based on false statements but similarly is not intended to increase the number of visas or foreign nationals who may come to the United States, nor can DHS foresee such an increase happening.

NEPA Final Rule Analysis

DHS and its components analyze proposed actions to determine whether the National Environmental Policy Act (NEPA) [58] applies to them and, if so, what degree of analysis is required. DHS Directive 023–01, Rev. 01 (Directive) and Instruction Manual 023–01–001–01, Rev. 01 (Instruction Manual) [59] establish the procedures DHS and its components use to comply with NEPA and the Council on Environmental Quality (CEQ) regulations for implementing NEPA.[60] The CEQ regulations allow Federal agencies to establish in their NEPA implementing procedures categories of actions (''categorical exclusions'') that experience has shown normally do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require preparation of an Environmental Assessment or Environmental Impact Statement.[61] Instruction Manual, Appendix A, Table 1 lists the DHS categorical exclusions.

Under DHS NEPA implementing procedures, for an action to be categorically excluded, it must satisfy each of the following three conditions: (1) the entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect.[62]

As discussed throughout this preamble, this final rule will provide for the equal chance of selection for all H–1B beneficiaries and improve the integrity of the H–1B registration selection process through beneficiary centric selection, will allow for start date flexibility for H–1B petitioners, and will expand the ability of USCIS to deny and/or revoke petitions based on false statements made not just in the H–1B petition, but also in the H–1B registration, LCA, or TLC (applicable to H–2 programs).

DHS considers these changes to be strictly administrative in nature, and finds they will have no significant impact on the environment, or any change in the environmental effect that will result from the final rule changes. DHS therefore finds this final rule clearly fits within categorical exclusion A3 established in the Department's implementing procedures.

Although, the amendments being put into place by this final rule were initially proposed as part of an NPRM [63] that included broader proposed reforms, these amendments can and will operate independently from the other proposed reforms and do not depend on those proposals being finalized. Inclusion of all proposed reforms in a single NPRM was for purposes of administrative efficiency and not an indication that the proposed regulatory amendments in this final rule are a necessary part of a larger regulatory action.

DHS plans to address the other proposed reforms included in the NPRM through a separate final rule in which it will also discuss NEPA. However, this rule and any subsequent final rule resulting from the NPRM are each stand-alone regulatory actions. In accordance with the Instruction Manual's NEPA implementing procedures, DHS has completed an evaluation of this rule to determine whether it involves one or more of the ten identified extraordinary circumstances [64] that present the potential for significant environmental impacts. DHS concludes from its analysis that no extraordinary circumstances are present requiring further environmental analysis and documentation. Therefore, this action is

[58] *See* Public Law 91–190, 42 U.S.C. 4321- 4347.

[59] *See* DHS, ''Implementing the National Environmental Policy Act,'' DHS Directive 023–01, Rev 01 (Oct. 31, 2014), and DHS Instruction Manual Rev. 01 (Nov. 6, 2014), *https://www.dhs.gov/publication/directive-023-01-rev-01-and-instruction-manual-023-01-001-01-rev-01-and-catex.*

[60] *See* 40 CFR parts 1500 through 1508.

[61] *See* 40 CFR 1501.4(a).

[62] *See* Instruction Manual, section V.B.2 (a–c).

[63] 88 FR 72870 (Oct. 23, 2023).

[64] i. A potentially significant effect on public health or safety; ii. A potentially significant effect on species or habitats protected by the ESA, Marine Mammal Protection Act, Migratory Bird Treaty Act, Magnuson-Stevens Fishery Conservation and Management Act, or other law protecting a species or habitat; iii. A potentially significant effect on historic properties (*e.g.,* districts, sites, buildings, structures, or objects) that are listed in or eligible for listing in the National Register of Historic Places, affects traditional cultural properties or sacred sites, or leads to the loss or destruction of a significant scientific, cultural, or historical resource; iv. A potentially significant effect on an environmentally sensitive area. v. A potential or threatened violation of a Federal, State, or local law or requirement imposed to protect the environment. Some examples of other requirements to consider are: a local noise control ordinance; the requirement to conform to an applicable State Implementation Plan for air quality standards; Federal, Tribal, State, or local requirements to control hazardous or toxic substances; and environmental permits; vi. An effect on the quality of the human environment that is likely to be highly controversial in terms of scientific validity, likely to be highly uncertain, or likely to involve unique or unknown environmental risks. This also includes effects that may result from the use of new technology or unproven technology. Controversy over, including public opposition to, a proposed action absent any demonstrable potential for significant environmental impacts does not itself constitute an extraordinary circumstance; vii. Extent to which a precedent is established for future actions with significant effects; viii. Significantly greater scope or size than normally experienced for this particular category of action; ix. Potential for significant degradation of already existing poor environmental conditions. Also, initiation of a potentially significant environmental degrading influence, activity, or effect in areas not already significantly modified from their natural condition; x. Whether the action is related to other actions with individually insignificant, but cumulatively significant impacts.

categorically excluded and no further NEPA analysis is required.

I. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3512, DHS must submit to the OMB, for review and approval, any reporting requirements inherent in a rule, unless they are exempt.

In compliance with the PRA, DHS published an NPRM on October 23, 2023, in which comments on the revisions to the information collections associated with this rulemaking were requested. Any comments received on information collections activities were related to the beneficiary centric changes and documentation required for establishing unique beneficiary identification. DHS responded to those comments in Section III. of this final rule. The information collection instruments that will be revised with this final rule are described below.

H–1B Registration Tool (OMB Control No. 1615–0144)

Overview of information collection:

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* H–1B Registration Tool.

(3) *Agency form number, if any, and the applicable component of DHS sponsoring the collection:* OMB–64; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. USCIS uses the data collected on this form to determine which employers will be informed that they may submit a USCIS Form I–129, Petition for Nonimmigrant Worker, for H–1B classification.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection H–1B Registration Tool (Businesses) is 20,950 and the estimated hour burden per response is 0.6 hours. The estimated total number of respondents for the information collection H–1B Registration Tool (Attorneys) is 19,339 and the estimated hour burden per response is 0.6 hours. The total number of responses (355,590) is estimated by averaging the total number of registrations received during the H–1B cap FYs 2021, 2022, and 2023.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection of information is 213,354 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $0.

Form I–129 (OMB Control No. 1615–0009)

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Nonimmigrant Worker.

(3) *Agency form number, if any, and the applicable component of DHS sponsoring the collection:* I–129, E–1/E–2 Classification Supplement, Trade Agreement Supplement, H Classification Supplement, H–1B and H–1B1 Data Collection and Filing Exemption Supplement, L Classification Supplement, O and P Classification Supplement, Q–1 Classification Supplement, and R–1 Classification Supplement; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. USCIS uses Form I–129 and accompanying supplements to determine whether the petitioner and beneficiary(ies) is (are) eligible for the nonimmigrant classification. A U.S. employer, or agent in some instances, may file a petition for nonimmigrant worker to employ foreign nationals under the following nonimmigrant classifications: H–1B, H–2A, H–2B, H–3, L–1, O–1, O–2, P–1, P–2, P–3, P–1S, P–2S, P–3S, Q–1, or R–1 nonimmigrant worker. The collection of this information is also required from a U.S. employer on a petition for an extension of stay or change of status for E–1, E–2, E–3, Free Trade H–1B1 Chile/Singapore nonimmigrants and TN (USMCA workers) who are in the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–129 is 294,751 and the estimated hour burden per response is 2.42 hours. The estimated total number of respondents for the information collection E–1/E–1 Classification Supplement is 4,760 and the estimated hour burden per response is 0.67 hours. The estimated total number of respondents for the information collection Trade Agreement Supplement is 3,057 and the estimated hour burden per response is 0.67 hours. The estimated total number of respondents for the information collection H Classification is 96,291 and the estimated hour burden per response is 2.07 hours. The estimated total number of respondents for the information collection H–1B and H–1B1 Data Collection and Filing Fee Exemption Supplement is 96,291 and the estimated hour burden per response is 1 hour. The estimated total number of respondents for the information collection L Classification Supplement is 37,831 and the estimated hour burden per response is 1.34 hours. The estimated total number of respondents for the information collection O and P Classification Supplement is 22,710 and the estimated hour burden per response is 1 hour. The estimated total number of respondents for the information collection Q–1 Classification Supplement is 155 and the estimated hour burden per response is 0.34 hours. The estimated total number of respondents for the information collection R–1 Classification Supplement is 6,635 and the estimated hour burden per response is 2.34 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection of information is 1,103,130 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $70,681,290.

VI. List of Subjects and Regulatory Amendments

List of Subjects in 8 CFR part 214

Administrative practice and procedure, Aliens, Cultural exchange program, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

Accordingly, DHS amends chapter I of title 8 of the Code of Federal Regulations as follows:

PART 214—NONIMMIGRANT CLASSES

■ 1. The authority citation for part 214 continues to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305, 1357, and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

■ 2. Amend § 214.2 by:

■ a. Revising paragraphs (h)(8)(iii)(A), (D) and (E);
■ b. Revising and republishing paragraph (h)(8)(v);
■ c. Revising paragraph (h)(10)(ii);
■ d. Adding new paragraph (h)(10)(iii);
■ e. Revising paragraphs (h)(11)(iii)(A)(*2*) and (*5*); and
■ f. Adding paragraph (h)(11)(iii)(A)(*6*).

The revisions and additions read as follows:

* * * * *

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(h) * * *

(8) * * *

(iii) * * *

(A) *Registration*—(*1*) *Registration requirement.* Except as provided in paragraph (h)(8)(iv) of this section, before a petitioner can file an H–1B cap-subject petition for a beneficiary who may be counted under section 214(g)(1)(A) of the Act (''H–1B regular cap'') or eligible for exemption under section 214(g)(5)(C) of the Act (''H–1B advanced degree exemption''), the petitioner must register to file a petition on behalf of a beneficiary electronically through the USCIS website (*www.uscis.gov*). To be eligible to file a petition for a beneficiary who may be counted against the H–1B regular cap or the H–1B advanced degree exemption for a particular fiscal year, a registration must be properly submitted in accordance with 8 CFR 103.2(a)(1), paragraph (h)(8)(iii) of this section, and the form instructions, for the same fiscal year.

(*2*) *Limitation on beneficiaries.* A prospective petitioner must electronically submit a separate registration for each beneficiary it seeks to register, and each beneficiary must be named. A petitioner may only submit one registration per beneficiary in any fiscal year. If a petitioner submits more than one registration per beneficiary in the same fiscal year, all registrations filed by that petitioner relating to that beneficiary for that fiscal year may be considered invalid, and USCIS may deny or revoke the approval of any H–1B petition filed for the beneficiary based on those registrations. If USCIS determines that registrations were submitted for the same beneficiary by the same or different registrants, but using different identifying information, USCIS may find those registrations invalid and deny or revoke the approval of any H–1B petition filed based on those registrations. Petitioners will be given notice and the opportunity to respond before USCIS denies or revokes the approval of a petition.

(*3*) *Initial registration period.* The annual initial registration period will last a minimum of 14 calendar days and will start at least 14 calendar days before the earliest date on which H–1B cap-subject petitions may be filed for a particular fiscal year, consistent with paragraph (h)(2)(i)(I) of this section. USCIS will announce the start and end dates of the initial registration period on the USCIS website at *www.uscis.gov* for each fiscal year. USCIS will announce the start of the initial registration period at least 30 calendar days in advance of such date.

(*4*) *Selecting registrations based on unique beneficiaries.* Registrations will be counted based on the number of unique beneficiaries who are registered. USCIS will separately notify each registrant that their registration on behalf of a beneficiary has been selected, and that the petitioner(s) may file a petition(s) for that beneficiary. A petitioner may file an H–1B cap-subject petition on behalf of a registered beneficiary only after their properly submitted registration for that beneficiary has been selected for that fiscal year.

(*i*) Should a random selection be necessary, as provided in paragraphs (h)(8)(iii)(A)(*5*)(*ii*), (h)(8)(iii)(A)(*6*)(*ii*), and (h)(8)(iii)(A)(*7*) of this section, each unique beneficiary will only be counted once towards the random selection of registrations, regardless of how many registrations were submitted for that beneficiary.

(*ii*) Registrations must include the beneficiary's valid passport information or valid travel document information, as specified in the form instructions. Each beneficiary must only be registered under one passport or travel document, and if or when the beneficiary is abroad, the passport information or travel document information must correspond to the passport or travel document the beneficiary intends to use to enter the United States.

(*5*) *Regular cap selection.* In determining whether there are enough registrations for unique beneficiaries to meet the H–1B regular cap, USCIS will consider all properly submitted registrations relating to beneficiaries that may be counted under section 214(g)(1)(A) of the Act, including those that may also be eligible for exemption under section 214(g)(5)(C) of the Act. Registrations will be counted based on the number of unique beneficiaries that are registered.

(*i*) *Fewer registrations than needed to meet the H–1B regular cap.* At the end of the annual initial registration period, if USCIS determines that it has received fewer registrations for unique beneficiaries than needed to meet the H–1B regular cap, USCIS will notify all petitioners that have properly registered that their registrations have been selected. USCIS will keep the registration period open beyond the initial registration period, until it determines that it has received a sufficient number of registrations for unique beneficiaries to meet the H–1B regular cap. Once USCIS has received a sufficient number of registrations for unique beneficiaries to meet the H–1B regular cap, USCIS will no longer accept registrations for petitions subject to the H–1B regular cap under section 214(g)(1)(A) of the Act. USCIS will monitor the number of registrations received and will notify the public of the date that USCIS has received the necessary number of registrations for unique beneficiaries (the ''final registration date''). The day the public is notified will not control the applicable final registration date. When necessary to ensure the fair and orderly allocation of numbers under section 214(g)(1)(A) of the Act, USCIS may randomly select the remaining number of registrations for unique beneficiaries deemed necessary to meet the H–1B regular cap from among the registrations received on the final registration date. This random selection will be made via computer-generated selection, based on the unique beneficiary.

(*ii*) *Sufficient registrations to meet the H–1B regular cap during initial registration period.* At the end of the initial registration period, if USCIS determines that it has received more than sufficient registrations for unique beneficiaries to meet the H–1B regular cap, USCIS will no longer accept registrations under section 214(g)(1)(A) of the Act and will notify the public of the final registration date. USCIS will randomly select from among the registrations properly submitted during the initial registration period the number of registrations for unique beneficiaries deemed necessary to meet the H–1B regular cap. This random selection will be made via computer-generated selection, based on the unique beneficiary.

(*6*) *Advanced degree exemption selection.* After USCIS has determined it will no longer accept registrations under section 214(g)(1)(A) of the Act, USCIS will determine whether there is a sufficient number of remaining registrations to meet the H–1B advanced degree exemption.

(*i*) *Fewer registrations than needed to meet the H–1B advanced degree exemption numerical limitation.* If

USCIS determines that it has received fewer registrations for unique beneficiaries than needed to meet the H–1B advanced degree exemption numerical limitation, USCIS will notify all petitioners that have properly registered that their registrations have been selected. USCIS will continue to accept registrations to file petitions for beneficiaries that may be eligible for the H–1B advanced degree exemption under section 214(g)(5)(C) of the Act until USCIS determines that it has received enough registrations for unique beneficiaries to meet the H–1B advanced degree exemption numerical limitation. USCIS will monitor the number of registrations received and will notify the public of the date that USCIS has received the necessary number of registrations for unique beneficiaries (the ''final registration date''). The day the public is notified will not control the applicable final registration date. When necessary to ensure the fair and orderly allocation of numbers under sections 214(g)(1)(A) and 214(g)(5)(C) of the Act, USCIS may randomly select the remaining number of registrations for unique beneficiaries deemed necessary to meet the H–1B advanced degree exemption numerical limitation from among the registrations properly submitted on the final registration date. This random selection will be made via computer-generated selection, based on the unique beneficiary.

(*ii*) *Sufficient registrations to meet the H–1B advanced degree exemption numerical limitation.* If USCIS determines that it has received more than enough registrations for unique beneficiaries to meet the H–1B advanced degree exemption numerical limitation, USCIS will no longer accept registrations that may be eligible for exemption under section 214(g)(5)(C) of the Act and will notify the public of the final registration date. USCIS will randomly select the number of registrations for unique beneficiaries needed to meet the H–1B advanced degree exemption numerical limitation from among the remaining registrations for unique beneficiaries who may be counted against the advanced degree exemption numerical limitation. This random selection will be made via computer-generated selection, based on the unique beneficiary.

(*7*) *Increase to the number of beneficiaries projected to meet the H–1B regular cap or advanced degree exemption allocations in a fiscal year.* Unselected registrations will remain on reserve for the applicable fiscal year. If USCIS determines that it needs to increase the number of registrations for unique beneficiaries projected to meet the H–1B regular cap or advanced degree exemption allocation, and select additional registrations for unique beneficiaries, USCIS will select from among the registrations that are on reserve a sufficient number to meet the H–1B regular cap or advanced degree exemption numerical limitation, as applicable. If all of the registrations on reserve are selected and there are still fewer registrations than needed to meet the H–1B regular cap or advanced degree exemption numerical limitation, as applicable, USCIS may reopen the applicable registration period until USCIS determines that it has received a sufficient number of registrations for unique beneficiaries projected as needed to meet the H–1B regular cap or advanced degree exemption numerical limitation. USCIS will monitor the number of registrations received and will notify the public of the date that USCIS has received the necessary number of registrations (the new ''final registration date''). The day the public is notified will not control the applicable final registration date. When necessary to ensure the fair and orderly allocation of numbers, USCIS may randomly select the remaining number of registrations for unique beneficiaries deemed necessary to meet the H–1B regular cap or advanced degree exemption numerical limitation from among the registrations properly submitted on the final registration date. If the registration period will be reopened, USCIS will announce the start of the re-opened registration period on the USCIS website at *www.uscis.gov.*

* * * * *

(D) *H–1B cap-subject petition filing following registration*—(*1*) *Filing procedures.* In addition to any other applicable requirements, a petitioner may file an H–1B petition for a beneficiary who may be counted under section 214(g)(1)(A) of the Act or eligible for exemption under section 214(g)(5)(C) of the Act only if the petition is based on a valid registration, which means that the registration was properly submitted in accordance with 8 CFR 103.2(a)(1), paragraph (h)(8)(iii) of this section, and the registration tool instructions; and was submitted by the petitioner, or its designated representative, on behalf of the beneficiary who was selected for that cap season by USCIS. A petitioner may not substitute the beneficiary named in the original registration or transfer the registration to another petitioner. Any H–1B petition filed on behalf of a beneficiary must contain and be supported by the same identifying information provided in the selected registration. Petitioners must submit evidence of the passport or travel document used at the time of registration to identify the beneficiary. In its discretion, USCIS may find that a change in identifying information in some circumstances would be permissible. Such circumstances could include, but are not limited to, a legal name change due to marriage, change in gender identity, or a change in passport number or expiration date due to renewal or replacement of a stolen passport, in between the time of registration and filing the petition. USCIS may deny or revoke the approval of an H–1B petition that does not meet these requirements.

(*2*) *Registration fee.* USCIS may deny or revoke the approval of an H–1B petition if it determines that the fee associated with the registration is declined, not reconciled, disputed, or otherwise invalid after submission. The registration fee is non-refundable and due at the time the registration is submitted.

(*3*) *Filing period.* An H–1B cap-subject petition must be properly filed within the filing period indicated on the relevant selection notice. The filing period for filing the H–1B cap-subject petition will be at least 90 days. If petitioners do not meet the requirements of this paragraph (h)(8)(iii)(D), USCIS may deny or reject the H–1B cap-subject petition.

(E) *Calculating the number of registrations needed to meet the H–1B regular cap and H–1B advanced degree exemption allocation.* When calculating the number of registrations for unique beneficiaries needed to meet the H–1B regular cap and the H–1B advanced degree exemption numerical limitation for a given fiscal year, USCIS will take into account historical data related to approvals, denials, revocations, and other relevant factors. If necessary, USCIS may increase those numbers throughout the fiscal year.

* * * * *

(v) *Severability.* (A) The requirement to submit a registration for an H–1B cap-subject petition and the selection process based on properly submitted registrations under paragraph (h)(8)(iii) of this section are intended to be severable from paragraph (h)(8)(iv) of this section. In the event paragraph (h)(8)(iii) of this section is not implemented, or in the event that paragraph (h)(8)(iv) of this section is not implemented, DHS intends that either of those provisions be implemented as an independent rule, without prejudice to

petitioners in the United States under this regulation, as consistent with law.

(B) DHS intends that the provisions governing the beneficiary centric selection process in paragraph (h)(8)(iii) of this section, the elimination of the requirement that the requested start date for the beneficiary be the first day for the applicable fiscal year in (h)(8)(iii)(A)(*4*), and the provisions governing the denial or revocation of H–1B petitions based on inaccurate, fraudulent, or misrepresented material facts in the H–1B petition, H–1B registration, temporary labor certification, or labor condition application in paragraphs (h)(10)(ii) and (iii) and (h)(11)(iii) of this section, respectively, published on February 2, 2024 be severable from one another. In the event that any of these provision(s) is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it should be construed so as to continue to give the maximum effect to the provision(s) permitted by law, unless any such provision is held to be wholly invalid and unenforceable, in which event the provision(s) should be severed from the remainder of this section and the holding should not affect the remainder of this section or the application of the other provisions to persons not similarly situated or to dissimilar circumstances.

* * * * *

(10) * * *

(ii) *Denial for statement of facts on the petition, H–1B registration, temporary labor certification, labor condition application, or invalid H–1B registration.* The petition will be denied if it is determined that the statements on the petition, H–1B registration (if applicable), the application for a temporary labor certification, or the labor condition application, were inaccurate, fraudulent, or misrepresented a material fact, including if the attestations on the registration are determined to be false. An H–1B cap-subject petition also will be denied if it is not based on a valid registration submitted by the petitioner (or its designated representative), or a successor in interest, for the beneficiary named or identified in the petition.

(iii) *Notice of denial.* The petitioner will be notified of the reasons for the denial and of the right to appeal the denial of the petition under 8 CFR part 103. There is no appeal from a decision to deny an extension of stay to the alien.

(11) * * *

(iii) * * *

(A) * * *

(*2*) The statement of facts contained in the petition, H–1B registration (if applicable), the application for a temporary labor certification, or the labor condition application, was not true and correct, inaccurate, fraudulent, or misrepresented a material fact, including if the attestations on the registration are determined to be false; or

* * * * *

(*5*) The approval of the petition violated paragraph (h) of this section or involved gross error; or

(*6*) The H–1B cap-subject petition was not based on a valid registration submitted by the petitioner (or its designated representative), or a successor in interest, for the beneficiary named or identified in the petition.

* * * * *

Alejandro N. Mayorkas,

Secretary, U.S. Department of Homeland Security.

[FR Doc. 2024–01770 Filed 1–30–24; 4:15 pm]

BILLING CODE 9111–97–P

FEDERAL REGISTER

Vol. 89 Friday,

No. 23 February 2, 2024

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 4 and 820

Medical Devices; Quality System Regulation Amendments; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 4 and 820

[Docket No. FDA–2021–N–0507]

RIN 0910–AH99

Medical Devices; Quality System Regulation Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation to harmonize and modernize the regulation. We are harmonizing to align more closely with the international consensus standard for devices by converging with the quality management system (QMS) requirements used by other regulatory authorities from other jurisdictions (*i.e.,* other countries). We are doing so by incorporating by reference an international standard specific for device quality management systems. Through this rulemaking we also establish additional requirements and make conforming edits to clarify the device CGMP requirements for such products. This action will continue our efforts to align our regulatory framework with that used by regulatory authorities in other jurisdictions to promote consistency in the regulation of devices and provide timelier introduction of safe, effective, high-quality devices for patients.

DATES: This rule is effective February 2, 2026. The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register February 2, 2026.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule 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:

With regard to the final rule: Keisha Thomas or Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2001, *Proposed-Device-QMSR-Rule@fda.hhs.gov.*

With regard to the information collection: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA has historically recognized the benefits of harmonization with other regulatory authorities and, over time, has taken a number of actions to promote consistency with its regulatory counterparts. As part of such activities, FDA is revising its medical device CGMP requirements as set forth in the QS regulation, codified in part 820 (21 CFR part 820). FDA is accomplishing this primarily by incorporating by reference the 2016 edition of ISO 13485 (ISO 13485). Through this rulemaking, FDA is harmonizing quality management system requirements for medical devices with requirements used by other regulatory authorities.

B. Summary of the Major Provisions of the Final Rule

We are amending part 820, primarily through incorporating by reference the quality management system requirements of ISO 13485.[1] We have determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act). As such, we are retaining the scope of the QS regulation, and amending many of the provisions. We are also amending the title of the regulation and establishing additional requirements and provisions that clarify certain expectations and certain concepts used in ISO 13485. These additions ensure that the incorporation by reference of ISO 13485 does not create inconsistencies with other applicable FDA requirements. This revised part 820 is referred to as the Quality Management System Regulation (QMSR). FDA has made conforming edits to part 4 (21 CFR part 4) to clarify the device Quality Management System (QMS) requirements for combination products. These edits do not impact the CGMP requirements for combination products.

C. Legal Authority

We are issuing this rule under the same authority that FDA initially invoked to issue the QS regulation and combination product regulations, as well as the general administrative provisions of the FD&C Act: 21 U.S.C. 351, 352, 353, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

D. Costs and Benefits

We estimate that the QMSR will result in an annualized net cost savings (benefits) of approximately $532 million at a 7 percent discount rate (cost savings: $540M, costs: $8.2M) and approximately $554 million in annualized net cost savings at a 3 percent discount rate (cost savings: $561M, costs: $7.29M). In addition to the cost savings to the medical device industry, the qualitative benefits of the

[1] In this rulemaking, FDA uses the terms below in the following manner: when referring to this rulemaking, FDA uses the term ''QMSR.'' When referring to the rule that was formerly effective, FDA uses the term ''QS regulation.'' Because both the QMSR and the former QS regulation are located in part 820, wherever possible, FDA has used the terms ''QS regulation'' and ''QMSR.''

rule include quicker access to newly developed medical devices for patients leading to improved quality of life of the consumers. The rule will also align part 820 with other related programs potentially contributing to additional cost savings.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
ANPRM	Advance Notice of Proposed Rulemaking.
CFR	Code of Federal Regulations.
CGMP	Current Good Manufacturing Practice.
CPG	Compliance Policy Guide.
EO	Executive Order.
EIR	Establishment Inspection Report.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	U.S. Food and Drug Administration.
GHTF	Global Harmonization Task Force.
GMP	Good Manufacturing Practice.
IMDFR	International Medical Device Regulators Forum.
ISO	International Organization for Standardization.
ISO 13485	Medical devices—Quality management systems—Requirements for regulatory purposes—ISO 13485:2016.
ISO 9000	Quality Management Systems—Fundamentals and Vocabulary—ISO 9000:2015.
ISO 14971	Medical Devices—Application of Risk Management to Medical Devices.
MDR	Medical Device Reporting.
MDSAP	Medical Device Single Audit Program.
OMB	Office of Management and Budget.
QMS	Quality Management System.
QMSR	Quality Management System Regulation.
QS	Quality System.
QSIT	Quality System Inspection Technique.
UDI	Unique Device Identifier/Unique Device Identification.

III. Background

A. Introduction

QMSs specify requirements to help manufacturers ensure that their products consistently meet applicable customer and regulatory requirements and specifications (Ref. 1). In the United States, authority to prescribe regulations requiring conformance to CGMP is found under section 520(f) of the FD&C Act (21 U.S.C. 360j(f)). In the **Federal Register** of July 21, 1978 (43 FR 31508), FDA issued a final rule for CGMP requirements, which also created part 820 (Ref. 2).

As described later in this section, FDA significantly revised part 820 in a final rule published in the **Federal Register** of October 7, 1996 (61 FR 52602) (1996 Final Rule), which established the QS regulation. The QS regulation included requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of devices intended for human use. These requirements have been effective in providing assurance that devices are safe and effective and otherwise in compliance with the FD&C Act. FDA has not undertaken a significant revision of part 820 since the 1996 Final Rule.

Also in 1996, ISO issued the first version of ISO 13485, ''Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001,'' as a voluntary consensus standard to specify, in conjunction with the application of ISO 9001, the QMS requirements for the design and development and, when relevant, installation and servicing of medical devices (Refs. 3 and 4). Over time, ISO 13485 has evolved into a stand-alone standard outlining QMS requirements for devices (Ref. 1).

With each revision, the requirements in ISO 13485 have become more closely aligned with, and similar to, the requirements set forth in FDA's QS regulation. This alignment and similarity are particularly true for the 2016 version of ISO 13485. Recognizing this progression, FDA sees an opportunity for regulatory harmonization by amending part 820 to incorporate by reference the QMS requirements of ISO 13485 and, thereby, replace the QS regulation with the new QMSR. ISO 13485 is used internationally by many regulatory authorities either as a foundation for or as that regulatory authority's QMS requirements for device manufacturers and is utilized in regulatory harmonization programs such as the Medical Device Single Audit Program (MDSAP), in which FDA and regulatory authorities from four other countries participate (Ref. 5).

The QS regulation applied to many different devices and, thus, did not prescribe in detail how a manufacturer was to design and manufacture a specific device. Rather, the regulation was developed to be a mandatory and flexible framework, requiring manufacturers to develop and follow procedures and processes, as appropriate to a given device, according to the current state-of-the-art for manufacturing and designing such a device. Successful compliance with this regulation provided the manufacturer with a framework for achieving quality throughout the organization (Ref. 1).

While the QS regulation effectively addressed the requirements for a QMS, FDA has long recognized the value of, and has been exploring ways to effect, global harmonization for the regulation of devices. For example, FDA has actively participated in the development of internationally harmonized documents and standards on risk management since their inception, including the development of the Global Harmonization Task Force (GHTF) guidance document entitled ''Implementation of Risk Management Principles and Activities Within a Quality Management System,'' dated May 20, 2005, which outlines the integration of a risk management system into a QMS (Ref. 6). FDA also participated in the development of the various versions of ISO 14971 ''Medical Devices—Application of Risk Management to Medical Devices'' (Ref. 7).

In 2012, FDA developed a voluntary audit report submission pilot program, which is no longer operational, in which FDA accepted a manufacturer's

ISO 13485:2003 audit report (Ref. 8). Through this program, FDA established the feasibility of using ISO 13485 audit reports in lieu of FDA's routine inspections covering the QS regulation requirements. Additionally, FDA participates in the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world focused on regulatory harmonization and convergence (Ref. 9). IMDRF developed MDSAP in 2012.

Under MDSAP, audits performed by third parties are conducted based on core ISO 13485 requirements with additional country-specific requirements. In determining whether to participate in MDSAP and which FDA-specific provisions were needed for the United States, FDA conducted a thorough review and comparison of ISO 13485 and the QS regulation and concluded that very few FDA-specific requirements needed to be added to this audit model, demonstrating not only the similarities between the QS regulation and ISO 13485, but also the comprehensive QMS approach provided by ISO 13485. This has allowed FDA to participate in MDSAP and accept certain MDSAP audits as a substitute for its own routine surveillance of device quality systems (Ref. 5).

Through participation in MDSAP, FDA has gained experience with ISO 13485 and determined that it provides a comprehensive and effective approach to establishing a QMS for medical devices. As such, in this rulemaking, FDA is amending the device CGMP requirements of part 820 by incorporating by reference the 2016 edition of ISO 13485. We are also publishing additional requirements that help connect and align ISO 13485 with other FDA requirements. The 2016 version of ISO 13485 provides requirements for a QMS that allow a manufacturer to demonstrate its ability to provide devices and related services that consistently meet customer requirements and regulatory requirements applicable to such devices and services (Ref. 1). These requirements can be used by ''an organization involved in one or more stages of the life cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices'' (Ref. 1).

FDA believes the global harmonization of medical device regulation can help provide safe, effective, and high-quality devices and contributes to public health through timelier patient access to such devices. Harmonizing differing regulations removes unnecessary duplicative regulatory requirements and impediments to market access and removes barriers to patient access and lowers costs.

B. Need for the Regulation

Device manufacturers registered with FDA must comply with part 820. In addition, registered manufacturers in many other jurisdictions and domestic manufacturers that export devices must comply with ISO 13485, which is substantially similar to the QS regulation. As a result, there is redundant effort for some manufacturers in complying with both the QS regulation and ISO 13485. The redundancy of effort to comply with two substantially similar requirements creates inefficiency. For example, FDA expects that the aligned requirements will reduce the burden on industry to prepare documents and/or records for inspections and audits. In addition, the final rule will result in establishments conducting internal audits and management reviews based on aligned requirements as opposed to auditing and assessing separately to comply with the requirements of the previous QS regulation and ISO 13485 individually. The harmonization of requirements will reduce training costs of industry in that internal training can now cover an aligned set of requirements. To address this inefficiency, we are incorporating by reference ISO 13485 to align substantially similar requirements. Although the requirements under the QS regulation are effective and substantially similar to those in ISO 13485, incorporating ISO 13485 by reference will further the Agency's goals for regulatory simplicity and global harmonization and should reduce burdens on regulated industry overall, thereby providing patients more efficient access to necessary devices (Ref. 9).

C. FDA's Current Regulatory Framework

The FD&C Act, as amended, and its implementing regulations establish a comprehensive system for the regulation of devices intended for human use. The device CGMP requirements in the QS regulation were authorized by section 520(f) of the FD&C Act, which was among the authorities added to the FD&C Act by the Medical Device Amendments of 1976 (Pub. L. 94–295). Under section 520(f) of the FD&C Act, FDA issued the QS regulation, which was last revised in 1996.

In addition, section 520(f)(1)(B) of the FD&C Act directs the Agency to afford the Device Good Manufacturing Practice Advisory Committee (DGMP Advisory Committee) an opportunity to submit recommendations for proposed CGMP regulations, to afford an opportunity for an oral hearing, and to ensure that such regulations conform, to the extent practicable, with internationally recognized standards defining QMSs, or parts of the standards, for devices (see 21 U.S.C. 360j(f)(1)(B)). The DGMP Advisory Committee reviews regulations proposed for promulgation regarding good manufacturing practices and makes recommendations to the Agency regarding the feasibility and reasonableness of the proposed regulations.

On March 2, 2022, the Agency convened a DGMP Advisory Committee meeting and afforded an opportunity for an oral hearing to discuss this proposal and to make recommendations that FDA considered when finalizing this rule (Ref. 10). The meeting included presentations by both FDA and stakeholders and also discussions regarding various topics, including the requirements within the proposed rule; the use of a consensus standard for regulatory purposes and accompanying considerations; impact to stakeholders; implementation questions related to education, training, inspections, and timing; as well as considerations for transition planning and options for guidance for stakeholders. The DGMP generally agreed with FDA's proposal for harmonization as set forth in the proposed rule and noted that using global standards can help increase overall compliance with regulatory requirements.

Further, the provisions of section 501(a)(2)(B) and (h) of the FD&C Act (21 U.S.C. 351(a)(2)(B) and (h)) require the manufacture of drugs and devices to comply with CGMP requirements, and section 520(f) of the FD&C Act specifically authorizes the issuance of CGMP regulations for devices, including device constituent parts of products that constitute a combination of a drug, device, and/or biological product, as defined in 21 CFR 3.2(e) (''combination products''). Combination products that include device constituent parts have a distinct regulatory framework for CGMP requirements because the product, by definition, also includes non-device constituent parts (*e.g.,* a drug or a biological product). In the **Federal Register** of January 22, 2013 (78 FR 4307), FDA issued a final rule codifying the CGMP requirements applicable to combination products at part 4. We issued the part 4 regulations, in part, under sections 501(a)(2)(B) and (h) and 520(f) of the FD&C Act, and we are

amending part 4 under the same authorities in this rulemaking.

The regulatory requirements for combination products arise from the statutory and regulatory requirements applicable to drugs, devices, and biological products, which retain their discrete regulatory identities when they are constituent parts of a combination product. At the same time, combination products comprise a distinct category of medical products that can be subject to specialized regulatory requirements, where appropriate. Specialized regulatory requirements for combination products generally are designed to address the overlaps and distinctions between the statutory and regulatory requirements applicable to the drug, device, and biological product constituent parts that comprise them. Part 4 clarifies the applicability of the various CGMP requirements to provide a streamlined option for practical implementation for co-packaged and single-entity combination products (see 78 FR 4307 at 4320, 81 FR 92603 and part 4). Because of the similarity of the drug and device CGMP requirements, FDA considers demonstrating compliance with one of these two sets of regulations (*e.g.,* device CGMP requirements) along with demonstrating compliance with the specified provisions from the other set (*e.g.,* drug CGMP requirements) identified in part 4 as demonstrating compliance with all CGMP requirements from both sets (see 78 FR 4307 at 4320 and § 4.4 (21 CFR 4.4)).

D. History of This Rulemaking

This rulemaking is the first major revision of part 820 since 1996. As previously described, FDA has had a longstanding interest and history of participation in efforts to harmonize its regulatory requirements with the requirements used by other regulatory authorities from other jurisdictions (*i.e.,* other countries). This rulemaking is a continuation of these efforts and harmonizes FDA's QMS regulation with requirements of the international standard ISO 13485, which is used by other regulatory authorities. Harmonizing FDA regulations with the ISO standard will have benefits for manufacturers because many firms producing devices for sale within the United States and abroad have to comply with both standards. This rule will require compliance with more closely aligned requirements.

On July 21, 1978, FDA issued a final rule in the **Federal Register** (43 FR 31508), establishing CGMP requirements for medical devices under section 520(f) of the FD&C Act. This rule became effective on December 18, 1978, and is codified under part 820.

The Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629) amended section 520(f) of the FD&C Act to provide FDA with the authority to add preproduction design controls to the CGMP regulation. This change in law was based on findings that a significant proportion of device recalls were attributable to faulty product design. The SMDA also added section 803 to the FD&C Act (21 U.S.C. 383), which, among other things, authorizes the Agency to enter into agreements with foreign countries to facilitate commerce in devices, and in such agreements, FDA must encourage the mutual recognition of GMP regulations under section 520(f) of the FD&C Act (see 21 U.S.C. 383(b)(1)).

To implement the SMDA changes to section 520(f) of the FD&C Act, FDA issued the 1996 Final Rule, which revised the CGMP requirements for medical devices and promulgated the QS regulation under part 820 in its previous form. As part of that revision, FDA added the design controls authorized by the SMDA in addition to other changes to achieve consistency with QMS requirements worldwide. At the time, the Agency sought to harmonize the CGMP regulations, to the extent possible, with the requirements for QMSs contained in then-applicable international standards. In particular, FDA worked closely with the GHTF and ISO Technical Committee 210 (TC 210) to develop a regulation consistent with both ISO 9001:1994, Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing; and the ISO committee draft (CD) revision of ISO/CD 13485 Quality systems—Medical Devices—Supplementary Requirements to ISO 9001 (see 61 FR 52602 at 52604).

In the **Federal Register** of February 23, 2022 (87 FR 10119), FDA published a proposed rule to amend the device CGMP requirements of the QS regulation. In this rulemaking, FDA is finalizing the proposed rule, taking into account the comments submitted to the docket and the recommendations from the DGMP Advisory Committee.

E. Summary of Comments to the Proposed Rule

In the **Federal Register** of February 23, 2022, FDA published a proposed rule to amend the device CGMP requirements of the QS regulation. The comment period for the proposed rule closed on May 24, 2022. FDA received many comments on the proposed rule from entities including medical device associations, industry, medical and healthcare professional associations, law firms, and other stakeholders, including individuals. While several comments object to particular sections or subsections of the proposed rule, almost all comments voice support for the objective of the proposed rule, to update and modernize the CGMP requirements of the QS regulations by incorporating ISO 13485.

Some comments raise concerns or request clarification regarding:

- the effective date of the rulemaking,
- the scope of the rulemaking,
- FDA's proposed definitions, as well as specific defined terms in the proposed rule,
- recordkeeping requirements,
- implementation, including the process for inspections conducted after the effective date,
- the implications of certification to ISO 13485, and
- traceability requirements.

F. General Overview of the Final Rule

We are amending part 820, primarily to incorporate by reference ISO 13485, Medical Devices—Quality Management System Requirements for Regulatory Purposes. While the QS regulation provided sufficient and effective requirements for the establishment and maintenance of a QMS, regulatory expectations for a QMS have evolved since the QS regulation was implemented over 20 years ago. By incorporating ISO 13485 by reference, we are explicitly requiring current internationally recognized regulatory expectations for QMS for devices subject to FDA's jurisdiction. This resulting regulation is referred to as the QMSR.

The previous QS requirements were, when taken in totality, substantially similar to the requirements of ISO 13485. Where ISO 13485 diverges from the QS regulation, these differences were generally consistent with the overall intent and purposes behind FDA's regulation of QMSs. Almost all requirements in the QS regulation corresponded to requirements within ISO 13485. Therefore, we are amending part 820 by incorporating by reference ISO 13485. Despite these changes, this rulemaking does not fundamentally alter the requirements for a QS that existed previously, and as noted throughout this document, FDA maintains its expectations regarding an effective QMS.

We recognize, however, that reliance on ISO 13485 without clarification or modification could create inconsistencies with FDA's statutory and regulatory framework. Therefore, as detailed in this rulemaking, we are

adding additional definitions and provisions.

One goal for this rulemaking is to simplify and streamline the regulation. Where possible, we either are accepting the incorporated requirement without modification or are creating a requirement that will supersede the correlating requirement in ISO 13485. There are a few exceptions where we are clarifying concepts or augmenting specific clauses in ISO 13485 but overall, we are not modifying the clauses in ISO 13485. This approach helps further regulatory convergence.

As discussed in section VI. of this document (regarding implementation), this rule is only amending the requirements of part 820 and does not impact our inspectional authority under section 704 of the FD&C Act (21 U.S.C. 374). We are also making conforming edits to part 4 to clarify the device QMS requirements for combination products. These edits do not impact the CGMP requirements for combination products.

FDA considered all comments received on the proposed rule and made changes, primarily for clarity and accuracy and to improve understanding of the requirements of the QMSR. On its own initiative, FDA is also making minor technical changes to further align the QMSR with requirements of the FD&C Act and its implementing regulations. The changes from the proposed rule include the following more significant revisions, additions, and removals to the codified section:

- Revise § 4.2 terms to replace ''QMSR for devices'' with ''QMSR.''
- Revise § 4.4(b)(1) to replace the term ''QMSR requirements'' with ''QMSR.''
- Revise § 4.4(b)(1)(i) to revise the term ''management responsibility'' by adding the phrase ''general requirements'' and adding § 820.10 to the section.
- Revise § 4.4(b)(1)(ii) to add the requirement that ''[t]he organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained.''
- Revise § 4.4(b)(1)(iv) to revise the term ''improvement'' by adding the phrase ''analysis of data'' and ''complaint handling'' and adding Clause 8.2.2 and § 820.35(a) to the section.
- Revise § 820.1(c) to align with statutory language in sections 501 and 801 (21 U.S.C. 381) of the FD&C Act.
- Revise § 820.3(a) to clarify use of definitions from ISO 13485 and ISO 9000 in this rulemaking.
- Remove from § 820.3(a) definitions for the terms ''customer,'' ''design validation,'' ''nonconformity,'' ''process agent,'' ''process validation,'' ''rework,'' ''top management,'' and ''verification.''
- Revise § 820.3(b) to clarify use of definitions from ISO 13485 and ISO 9000 in this rulemaking.
- Remove from § 820.3(b) the definition for the term ''product'' and add to § 820.3(b) the definition for the term ''rework.''
- Incorporate certain portions of proposed § 820.15, Clarification of Concepts, into § 820.3(b), not including § 820.15(c), ''validation of processes.'' Delete proposed § 820.15.
- Revise clarification of term ''safety and performance'' in § 820.3(b) to apply only to Clause 0.1 of ISO 13485.
- Add to § 820.3(b) clarification of term ''implantable medical device.''
- Remove from § 820.35 the requirement that a manufacturer must ''obtain the signature for each individual who approved or re-approved the record, and the date of such approval, on that record.''
- Revise § 820.35(a) to clarify expectations for record keeping related to complaint handling.
- Revise § 820.35(a)(6) to add ''correction.''
- Revise § 820.45 to replace the term ''establish'' with the term ''document,'' and replace the term ''where appropriate'' with the term ''as appropriate.''
- Revise § 820.45(c) to remove the term ''immediately'' with respect to inspection of labeling and packaging.

G. Incorporation by Reference

FDA is incorporating by reference the International Standard, ISO 13485:2016(E), *Medical devices—Quality management systems—Requirements for regulatory purposes,* Third Edition, 2016–03–01. ISO is an independent, nongovernmental international organization with a membership of national standards bodies. ISO 13485 specifies requirements for a QSM that can be used by a manufacturer involved in one or more stages of the life cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, or provision of associated activities. Incorporating ISO 13485 by reference in the QMSR will reduce the volume of material published in the Code of Federal Regulations (CFR) and it will have the same force and effect as language explicitly stated in the codified.

FDA is also incorporating by reference Clause 3 of ISO 9000:2015(E), *Quality management systems—Fundamentals and vocabulary,* (ISO 9000) (Ref. 11). ISO 9000 contains terms and definitions that are indispensable for the application of ISO 13485.

You may view ISO 13485 and ISO 9000 at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The materials can also be read in a read-only format at the American National Standards Institute (ANSI) Incorporated by Reference (IBR) Portal, *https://ibr.ansi.org/Standards/iso1.aspx,* or you may purchase a copy of the materials from the International Organization for Standardization, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; +41–22–749–01–11; *customerservice@iso.org, https://www.iso.org/store.html.* In addition, the terms and definitions given in ISO 9000 are available for viewing, without cost, at *https://www.iso.org/obp/ui#iso:std:iso:9000:ed-4:v1:en.*

FDA is incorporating by reference the current 2016 version of ISO 13485 and the current 2015 version of Clause 3 of ISO 9000. Any future revisions to these standards would need to be evaluated to determine the impact of the changes and whether this rule should be amended. If deemed necessary and appropriate, FDA will amend the final regulation in accordance with Federal law, including the Administrative Procedure Act (5 U.S.C. 553), and obtain approval of any changes to the incorporation by reference in accordance with 1 CFR part 51.

IV. Legal Authority

We are issuing this rule under the same authority that FDA initially invoked to issue the previous Quality System Regulation (part 820) and Regulation of Combination Products (part 4), as well as the general administrative provisions of the FD&C Act: 21 U.S.C. 321, 351, 352, 353, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360*l,* 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

V. Comments on the Proposed Rule and FDA Response

We received fewer than 100 timely filed comments on the proposed rule, each containing one or more comments on one or more issues. We received comments from medical device associations, industry, medical and healthcare professional associations, law firms, and other stakeholders, including individuals.

We describe and respond to the comments in this section. We have numbered each comment to help distinguish between different

comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

A. General Comments on Proposed Rule

(Comment 1) FDA received many comments that express support for the proposed QMSR. Many comments made general remarks supporting the proposed rule without focusing on a particular provision. Many comments agreed with FDA's goal to harmonize the QMSR with an internationally recognized standard. Multiple commenters agreed with FDA that this rulemaking will streamline regulations regarding quality management systems. Some comments express support for the reduced administrative burden of complying with multiple regulatory schemes. Other comments express support for the provisions of the rulemaking addressing risk management. Some comments express hope that FDA's rulemaking sets an example for other regulators, and expressed their desire that the rulemaking will inspire other regulators to follow a similar approach. Some commenters opined that international harmonization would enhance competition and help remove barriers to market access; another noted that harmonization will improve imported devices' compliance with regulatory requirements; and some commenters noted that the rule will help to ensure safe and effective devices.

(Response) FDA appreciates the public support for the proposed rulemaking. FDA notes that harmonizing the regulation of devices will help provide safe, effective, and high-quality devices, contributing to public health through timelier access for patients. FDA agrees that harmonizing regulations from different regulatory jurisdictions will remove unnecessary duplicative regulatory requirements and may limit impediments to market access, resulting in increased competition. Reducing barriers to patient access and increasing competition have the potential to bring down costs as well. FDA believes that the more explicit integration of risk management throughout ISO 13485 and incorporated into the QMSR will help best meet the needs of patients and users and facilitate access to quality devices along with the progress of science and technology.

B. Scope

(Comment 2) FDA received several comments regarding the scope of the QMSR. One commenter acknowledged that this rulemaking has not changed the scope of this regulation from the QS regulation, but suggested that FDA does not have legal authority to extend the QMSR to components or parts of finished devices, should the need arise.

(Response) FDA agrees with the portion of the comment that notes that the scope of the rule is appropriate and unchanged from the QS regulation.

FDA disagrees with the portion of the comment suggesting that FDA does not have the legal authority to extend the scope of the rule to components or parts of finished devices, should that become appropriate. FDA's legal authority to promulgate the QMSR derives from its statutory authority to develop regulations to assure that a device conforms to CGMP, to assure that the device will be safe and effective and otherwise in compliance with the FD&C Act. See section 520(f) of the FD&C Act. Section 201(h)(1) of the FD&C Act (21 U.S.C. 321(h)(1)) defines a device to include any component, part, or accessory of that device. Thus, while FDA's authority to promulgate quality systems regulations for devices extends to the components and parts of those devices, FDA has chosen, in this regulation, not to require components and parts to comply with the requirements of this rulemaking. FDA's determination not to extend this regulation to manufacturers of components and parts does not preclude any contract between manufacturers that requires compliance with this rulemaking and is consistent with Clause 0.1 of ISO 13485. This scope also is consistent with the previous scope in the QS Regulation. See also section IV. Limiting the application of that authority to the finished products that are within the scope of this rulemaking, however, does not alter the broader authority granted by the FD&C Act.

(Comment 3) FDA received several comments regarding specific entities within and outside the scope of the QMSR. One comment recommended that FDA should incorporate third-party servicers and refurbishers into the scope of this rulemaking. Another comment recommended that FDA extend the scope of the regulation to any entity required to register.

(Response) FDA disagrees with the comments that recommend FDA change the scope of the regulation to include third-party servicers and refurbishers. FDA has considered the comment's observation that ISO 13485 requires manufacturers who require servicing to document those processes and verify that such requirements are met. However, ISO 13485 does not impose the entirety of its requirements on third-party servicers or refurbishers, and because the purpose of this rulemaking is both to harmonize with international standards where possible and to retain the scope of the QS regulation, at this time FDA declines to incorporate third-party servicers and refurbishers into this rulemaking.

FDA has also considered the comment asking the Agency to apply the QMSR rulemaking to all entities required to register under section 510 of the FD&C Act (21 U.S.C. 360(h)). The Agency disagrees; the scope of the QMSR and the scope of the registration requirements serve different objectives. Section 510 of the FD&C Act requires all entities that manufacture, prepare, propagate, compound, or process devices to register their establishments, unless that entity and/or its activities are exempted by section 510(g) of the FD&C Act. FDA has determined that registering manufacturing entities is important, because knowing where devices are made helps FDA to conduct both pre- and postmarket inspections, which help to ensure that devices are manufactured in a safe and effective manner.

Section 520(f) of the FD&C Act addresses more activities than those enumerated in section 510, and makes the entities participating in those broader categories subject to the QMSR. Entities who, among other things, design, package, validate, manufacture, and store devices must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. Therefore, FDA disagrees that it would be appropriate to use registration requirements to determine which entities are subject to the QMSR.

(Comment 4) A comment asked FDA to discuss how the least burdensome concept was considered in the rulemaking.

(Response) As FDA has explained in the guidance document entitled ''The Least Burdensome Provisions: Concept and Principles,'' the least burdensome principles should be consistently and widely applied to the regulation of medical devices to help remove or reduce unnecessary burdens so that patients can have earlier and continued access to high-quality, safe, and effective devices (Ref. 12). This rulemaking to develop and use standards published by international

development organizations intends to converge and harmonize international medical device standards, and it is consistent with the least burdensome principles stated in the Agency's guidance document. As stated in the economic analysis, we believe this harmonization can help reduce overall documentation burdens on manufacturers without compromising safety and effectiveness.

(Comment 5) One commenter noted that while manufacturers of components or parts of finished devices are not subject to this rule, FDA should direct such manufacturers to any and all specific regulatory provisions that manufacturers of such devices should consider. Another comment requested that FDA define the term ''appropriate,'' as that term is used in the QMSR to note that manufacturers of components or parts of finished devices are encouraged to consider provisions of this regulation ''as appropriate.''

(Response) FDA agrees that manufacturers of components or parts of finished devices are not subject to the QMSR. We also note that, although the scope of the QMSR remains unchanged, FDA has the legal authority to inspect component manufacturers under the FD&C Act should the need arise. However, FDA encourages manufacturers to consider provisions of this regulation as appropriate. FDA declines to specify in this rulemaking the specific provisions ''appropriate for'' manufacturers of components or parts of finished device. FDA encourages manufacturers of components and parts of finished devices subject to the QMSR to also review this rule and consider its provisions as guidance, and to develop and follow processes and procedures aligned with the current best practices for manufacturing and designing that are applicable to such component or part. Voluntary compliance with the QMSR will provide manufacturers of components or parts of finished devices a framework for achieving quality throughout the organization. FDA notes that because ISO 13485 clarifies the term ''as appropriate'' in section 0.2, ''Clarification of concepts,'' in the manner requested by the commenter, we do not need to add such a definition to this rule.

(Comment 6) A commenter asked for examples of a clause in ISO 13485 conflicting with a provision of the FD&C Act and/or its implementing regulations, where FDA would consider the FD&C Act and/or its implementing regulations to control.

(Response) In response to the comment seeking clarification about how FDA will address any conflict between a clause of ISO 13485 and any provision of the FD&C Act, FDA notes that, to the extent that any clauses of ISO 13485 conflict with any provisions of the FD&C Act and/or its implementing regulations, the FD&C Act and/or its implementing regulations will control. Elsewhere in this rulemaking, FDA gives two such examples: (1) the definitions of ''device'' and ''labeling,'' in sections 201(h) and (m) of the FD&C Act, respectively, supersede the correlating definitions for ''medical device'' and ''labelling'' in ISO 13485; and (2) although ISO 13485 often refers to ''safety and performance'' as a standard to measure medical devices, we have clarified in response to Comment 51 that FDA construes ''safety and performance'' in Clause 0.1 of ISO 13485 to mean the same as ''safety and effectiveness'' in section 520(f) of the FD&C Act.

When there is a conflict between regulations in part 820 and a specifically applicable regulation located elsewhere in Chapter I of Title 21 of the CFR, the regulations that specifically apply to the device in question supersede other generally applicable requirements that conflict. A reader should not interpret this provision to mean that the specifically applicable regulation renders the rest of the part 820 regulation completely inapplicable; the generally applicable part 820 regulations apply to the extent they do not otherwise conflict with the specifically applicable regulation.

C. Incorporation by Reference

(Comment 7) FDA received several comments opining that, for various reasons, it is inappropriate for FDA to incorporate ISO 13485 by reference. Some of those comments claim that the standard is not meant to establish regulatory requirements. Others suggest that ISO 13485 is inconsistent with the MDSAP, and thus utilizing ISO 13485 to set regulatory requirements creates a conflict with that program.

(Response) FDA disagrees with the comments. Incorporation by reference is used primarily to enable Federal Agencies to give legal effect to privately developed technical standards or materials that are published elsewhere. Congress authorized incorporation by reference in the Freedom of Information Act (5 U.S.C. 552) to reduce the volume of material published in the **Federal Register** and CFR (see 5 U.S.C. 552(a) and 1 CFR part 51). The legal effect of incorporation by reference is that the material is treated as if it were published in the **Federal Register** and CFR. This material, like any other properly issued rule, has the force and effect of law.

FDA is utilizing the standard appropriately to form the basis of regulatory requirements. FDA notes that manner. In addition, ISO 13485 instructs that ''this International Standard can also be used . . . to assess the organization's ability to meet customer and regulatory requirements . . .'' (Ref. 1), at Clause 0.1. ISO 13485 acknowledges that there may be different applicable regulatory requirements for any individual jurisdiction. For example, Clause 0.1 of the standard states with respect to definitions, ''the definitions in applicable regulatory requirements differ from nation to nation and region to region. The [manufacturer] needs to understand how the definitions in this International Standard will be interpreted in light of regulatory definitions in the jurisdictions in which the medical devices are made available.''

FDA also disagrees that incorporating ISO 13485 creates a conflict with MDSAP.

MDSAP sets ISO 13485 as its core requirements, but MDSAP also allows for additional country-specific requirements for each jurisdiction that uses the standard. FDA is acting consistently with that flexibility by incorporating ISO 13485 with the additional requirements appropriate for compliance with the FD&C Act and its implementing regulations. FDA notes that it intends to assess its policies, procedures, and guidance documents, including any documents that address the MDSAP program, which may be impacted by this rulemaking and where appropriate may amend such documents in accordance with applicable procedures.

(Comment 8) Several commenters noted the manner in which the current rulemaking impacts their compliance obligations in the following ways:

(1) some commenters asked FDA to confirm that compliance with the QMSR satisfies ISO 13485 requirements;

(2) other commenters asked FDA to confirm that compliance with ISO 13485 demonstrates compliance with the QMSR; and

(3) additional commenters asked FDA to clarify whether compliance with the QMSR demonstrates compliance with other countries' regulatory requirements.

(Response) FDA responds to the commenters according to the numbered questions outlined above:

(1) FDA partially agrees with the comment. FDA agrees that harmonizing part 820 with ISO 13485 by

incorporating ISO 13485 by reference will create an aligned set of requirements, instead of two different ones. The redundancy of effort to comply with two substantially similar requirements creates inefficiency. To address this inefficiency, we are incorporating by reference ISO 13485 requirements in the QMSR. FDA expects that compliance with the QMSR will largely satisfy the standard set forth at ISO 13485. See also Comment 79.

(2) FDA disagrees with the comment and confirms that compliance only with ISO 13485 does not fully satisfy the QMSR. With the incorporation of ISO 13485 in the QMSR, the requirements of ISO 13485 become the foundational requirements for device CGMPs. FDA has added limited additional requirements to the QMSR where appropriate, and thus device manufacturers must meet those additional QMSR requirements in addition to those set forth in ISO 13485 (see *e.g.,* § 820.10(b)(i) through (iv)). Any additional requirements are intended to help manufacturers satisfy requirements within the FD&C Act or other FDA regulations. FDA also refers the commenter to FDA's response to specific comments more fully set forth later in this rulemaking. FDA notes, as is stated elsewhere in this rulemaking, that manufacturers are responsible for complying with all the applicable requirements of the FD&C Act and its implementing regulations.

(3) It is inappropriate for FDA to take a position in this rulemaking on whether compliance with ISO 13485 will meet any other jurisdiction's regulatory or statutory or legal requirements. As stated above, FDA cannot provide any assurances that meeting the QMSR or ISO 13485 demonstrates compliance with any other regulatory authority's requirements.

(Comment 9) Commenters inquired whether incorporating ISO 13485 by reference also means that FDA is incorporating any of the additional standards referenced in ISO 13485.

(Response) In response to comments received, in this rulemaking, FDA is incorporating Clause 3 of ISO 9000, in addition to ISO 13485, by reference. Therefore, consistent with Clause 3 of ISO 13485, unless otherwise specified in this rulemaking, the terms and definitions given in Clause 3 of ISO 9000 apply. Aside from Clause 3 of ISO 9000, FDA does not, in this rulemaking, incorporate ISO 14971 or any other standards referenced by, or listed as a source in, ISO 13485, but acknowledges that these other standards may be helpful in understanding application of ISO 13485.

(Comment 10) Comments suggested that FDA should not utilize any notes included in ISO 13485 as statutory requirements.

(Response) FDA agrees with the comment that the notes do not set forth statutory or other legal requirements. However, the notes provide an explanation for the provisions of ISO 13485, and those explanations can be helpful for understanding those provisions.

(Comment 11) One comment recommended that FDA incorporate only certain sections of the ISO 13485 introduction, which the commenter described as ''key parts'' of the introduction. In particular, the comment requested that FDA clarify whether FDA intends to incorporate Clauses 0.1 (General), 0.2 (Clarification of Concepts), and 0.4 (Relationship with ISO 9001) of the Introduction to ISO 13485.

(Response) FDA disagrees with the comment recommending that FDA incorporate only certain sections of the ISO 13485 introduction. This final rule incorporates the entire introduction from ISO 13485, which sets forth important concepts. FDA confirms that the QMSR incorporates ISO 13485:2016 by reference, including Clauses 0.1 (General), 0.2 (Clarification of Concepts), and 0.4 (Relationship with ISO 9001) of the Introduction of the standard.

(Comment 12) One commenter recommended that FDA retain in the QMSR § 820.100(a)(6) and (7) from the QS regulation, and noted that these provisions are not specifically listed in ISO 13485. The commenter stated that retaining these provisions was both important and beneficial to a quality management system to ensure that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.

(Response) FDA agrees that § 820.100(a)(6) and (7) of the QS regulation, which require that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of the product or the prevention of such problems and that relevant information on quality problems, as well as corrective and preventative actions, is submitted for management review, are not specifically listed in ISO 13485 but disagrees that the substance of those provisions is not accounted for in ISO 13485 and, thus, in the QMSR. Clauses 8.2.2, 8.5.2, and 8.3.1 of ISO 13485 address investigations of complaints, sharing relevant information between the organization and any external party involved in the complaints, determining the need to investigate nonconformities and any need to notify an external party responsible for a nonconformity, and evaluating any need for actions to ensure that nonconformities do not recur. Also, FDA notes that use error may be a type of nonconformity and may require investigation, as appropriate.

Nonconforming product discovered before or after distribution should be investigated to the degree commensurate with the significance and risk of the nonconformity, consistent with Clause 8.3 of ISO 13485 and its subclauses. At times an in-depth investigation will be necessary, while at other times a simple investigation, followed by trend analysis or other appropriate tools will be acceptable. Consistent with Clauses 8.2.5 and 8.2.6 of ISO 13485, among other things, the requirement for measurement and monitoring applies to process and quality system nonconformities, as well as product nonconformities. For example, if a molding process with its known capabilities has a normal 5 percent rejection rate and that rate rises to 10 percent, an investigation into the nonconformance of the process must be performed. We also note that, consistent with Clause 8.3.2 of ISO 13485, acceptance by concession of nonconforming product is allowed only if ''justification is provided, approval is obtained and applicable regulatory requirements are met.'' FDA believes that the justification should be based on scientific evidence, which a manufacturer should be prepared to provide upon request. Concessions should be closely monitored and not become accepted practice.

(Comment 13) Commenters suggested that the QMSR does not emphasize the importance of ensuring that personnel who perform verification and validation be qualified and trained, as set forth at § 820.20(b)(2) of the QS regulation. One commenter noted that ISO 13485 does not include the term ''special process'' and recommended that the QMSR use that phrase, as the commenter believed that phrase is set forth at § 820.75(b)(1) of the QS regulation.

(Response) FDA agrees with the commenter that it is important to have competent personnel to conduct validation activities and adds that one of the principles on which the quality systems regulation is based is that all processes require some degree of

qualification, verification, or validation, and manufacturers should not rely solely on inspection and testing to ensure processes are adequate for their intended use. FDA considers Clause 6.2 of ISO 13485 to capture the intent of the previous § 820.75(b)(1) adequately, by requiring that any individuals doing work that impacts quality should be competent on the basis of appropriate education, training, skills, and expertise. Examples of such individuals may include internal and external personnel performing work impacting product quality, full-time and part-time personnel, contractors, and/or consultants. All education, training, skills, and experience of employees need to be carefully recorded.

FDA disagrees that it is necessary to keep the language of § 820.20(b)(2) from the QS regulation in the QMSR to maintain the requirements of the section, which are addressed by Clause 6.2 of ISO 13485. FDA also agrees that the term ''special process'' does not appear in ISO 13485 but would like to clarify that the phrase ''special process'' does not appear in § 820.75(b)(1) of the QS regulation, and thus, no additional changes to the rule are necessary to address this comment.

(Comment 14) One commenter recommended that FDA retain in the QMSR the provisions of the previous § 820.150, as the commenter suggested that ISO 13485 lacks requirements to prevent a manufacturer from using an obsolete product.

(Response) FDA agrees that the specific language from the previous § 820.150 does not appear in ISO 13485 but disagrees that the same concept is not covered within ISO 13485. Specifically, Clause 7.5.11 of ISO 13485 allows a device manufacturer to have the flexibility to use a risk-based approach to develop a process to preserve conformity of devices to requirements during processing, storage, handling, and distribution. FDA emphasizes that this process should take into consideration that a nonconformity may not always rise to the level of a product defect or failure, and we note that a product defect or failure will typically constitute a nonconformity. This process should ensure that devices distributed conform to established distribution criteria and are not otherwise obsolete.

More broadly, we note that one objective of the QMSR is to correct and prevent poor practices, not simply bad product. Consistent with Clauses 8.1, 8.2.4, 8.2.5 and 8.2.6, FDA expects that correction and prevention of unacceptable QS practices should result in fewer nonconformities related to product. These and other provisions of the QMSR address problems within the QS itself. As additional examples, FDA expects that a QMSR-adherent QMS will identify and correct improper personnel training, the failure to follow procedures, and inadequate procedures, among other things.

(Comment 15) One commenter suggested that FDA maintain the titles and subparts of the QS regulation, which the commenter further suggested would avoid the need to substantially modify existing cross references and citations within industry and Agency systems.

(Response) FDA disagrees with the comment and suggestion. The titles and subparts have been modified as set forth in the codified language to be consistent and to harmonize with the terminology in ISO 13485. Thus, this rulemaking titles part 820 ''PART 820 QUALITY MANAGEMENT SYSTEM REGULATION'' and includes Subpart A—General Provisions, and Subpart B—Supplemental Provisions. Subparts C through O of the QS regulation have been removed and reserved.

(Comment 16) Several commenters inquired as to how FDA intended to manage updates to ISO 13485, and some commenters suggested that FDA utilize this rulemaking to communicate in advance its plan for managing any future revisions to the standard.

(Response) FDA agrees that ISO 13485 will likely be updated, but disagrees that this rulemaking is the appropriate instrument for addressing how FDA will address any such future revisions. Any future revisions to this standard would need to be evaluated to determine the impact of the changes and whether the QMSR should be amended. If deemed appropriate, FDA will update this regulation in accordance with Federal law, including the Administrative Procedure Act (5 U.S.C. 553), and obtain approval of any changes to the incorporation by reference in accordance with 1 CFR part 51. Also, FDA actively participates in the ISO technical committee responsible for ISO 13485 (ISO TC 210). As a participant in ISO TC 210, we are actively monitoring and engaged in the process of making changes to the standard.

(Comment 17) FDA received a comment disagreeing that a revision to part 820 was needed given the similarity of the requirements between ISO 13485 and the QS regulation.

(Response) FDA recognizes that the effort necessary to comply with two substantially similar requirements can lead to some potential redundancy and inefficiency. To reduce this potential for inefficiency while retaining the same high standards for safety and effectiveness for medical devices, we have incorporated by reference ISO 13485 requirements into part 820 so that compliance with ISO 13485 and the new QMSR would more closely align. Although the requirements under the QS regulation were effective and substantially similar to those in ISO 13485, incorporating ISO 13485 by reference furthers the Agency's goals for regulatory simplicity and global harmonization and should reduce burdens on regulated industry, thereby providing patients more timely access to safe and effective medical devices.

(Comment 18) Commenters suggested that, in this rulemaking, FDA map the requirements of the QS regulation to ISO 13485 and/or the QMSR. Comments noted that ISO 13485 differs in wording, phraseology, and organization from the QMSR.

(Response) FDA agrees with the comments that note there are some differences between the QS regulation, the QMSR, and ISO 13485, but disagrees with the comments that suggest FDA should map the requirements of the QS regulation to ISO 13485 and/or the QMSR. The QMSR replaces the QS regulation, and FDA disagrees that providing a 1-to-1 comparison of the former regulation would be useful to understand and comply with the new QMSR. The concepts and requirements contained in the QS regulation, when viewed holistically, are contained in ISO 13485. However, ISO 13485 is organized differently from the QS regulation such that providing a direct comparison of the former QS regulation to the QMSR would be cumbersome and not a useful tool to help firms comply with this rulemaking.

The QMSR requirements are, when taken in totality, substantially similar to the requirements of ISO 13485. Where FDA's statutory framework requires additions to ISO 13485, these requirements are generally consistent with the overall intent and purposes behind FDA's regulation of QMSs. This rulemaking does not fundamentally alter the requirements for a QS that exist in either the former QS regulation or the new QMSR. This rulemaking harmonizes the QS regulation with the QMS requirements of ISO 13485, while continuing to provide the same level of assurance of safety and effectiveness under the FD&C Act and its implementing regulations.

(Comment 19) FDA received several comments regarding the role of risk and risk management in the QMSR. Some comments agreed that the embedded risk management concepts present in ISO 13485 emphasize risk management

throughout the total product life cycle, while another disagreed that ISO 13485 requires a complete risk management system. One comment suggested that FDA's guidance documents addressing risk management may conflict or overlap after this rulemaking. Another comment suggested that FDA is shifting its focus to speed of access, rather than quality of devices.

(Response) FDA disagrees that it has changed its primary objective; FDA's expectations associated with risk management remain consistent: providing reasonable assurance of safety and effectiveness through the appropriate regulatory processes. FDA agrees that the embedded risk management concepts present in ISO 13485 emphasize risk management throughout the total product life cycle. Although the integration of risk management principles throughout ISO 13485 does not represent a shift in philosophy, the explicit integration of risk management throughout the clauses of ISO 13485 more explicitly establishes a requirement for risk management to occur throughout a QMS and should help industry develop more effective total product life-cycle risk management systems. Effective risk management systems provide the framework for sound decision making within a QMS and provide assurance that the devices will be safe and effective (see section 520(f) of the FD&C Act). The QS regulation explicitly addressed risk management activities in the former § 820.30(g) (21 CFR 820.30(g)). In adopting ISO 13485, the QMSR incorporates risk management throughout its requirements and explicitly emphasizes risk management activities and risk-based decision making as important elements of an effective quality system (see *e.g.,* Clauses 4.1, 7.1, 7.3, 7.4, 7.5, 7.6, and 8.2 and certain subclauses therein of ISO 13485).

FDA also disagrees that ISO 13485 does not require a complete risk management system. Because the standard is intended to guide development of a quality system to meet regulatory requirements for medical devices, the ISO prioritizes that an effective quality system systematically identify, analyze, evaluate, control, and monitor risk throughout the product life cycle to ensure that the devices they manufacture are safe and effective. This includes the review and update of risk documentation when a manufacturer becomes aware of previously unforeseen risks or new information that suggests that known risks need to be updated to ensure appropriate control measures are implemented.

In response to the comment suggesting that FDA's guidance documents may need to be reevaluated after this rulemaking, FDA notes that it intends to assess all of its policies, procedures, regulations, and guidance documents that are impacted by the QMSR, and make conforming revisions, as appropriate.

(Comment 20) One commenter noted that ISO 13485 separates the terms ''corrective action'' and ''preventive action,'' suggested that FDA should not combine the two concepts in the QMSR's corrective action process, and further suggested that use of the term ''Preventive Action'' in ISO 13485 is not consistent with FDA's previous use of that term.

(Response) FDA agrees with the portion of the comment that notes that ISO 13485 has one Clause outlining expectations regarding corrective action (Clause 8.5.2) and has another Clause outlining the expectations regarding preventive action (Clause 8.5.3). FDA has incorporated the corrective action and preventive action requirements of ISO 13485 by reference into the QMSR and disagrees that it has combined the two subjects in the manner the commenter describes. In the QS regulation, FDA's prior interpretation of the term ''preventive action'' did not apply solely to preventing recurrence of quality problems, and we disagree that adoption of the definition in ISO 13485 represents a change in expectation. FDA continues to believe that it is essential that the manufacturer establish procedures for implementing corrective action and preventive action, and that these procedures must provide for control and action to be taken on quality systems, processes, and products with actual or potential nonconformities.

The degree of corrective or preventive action taken to eliminate or minimize actual or potential nonconformities shall be appropriate to the magnitude of the problem and commensurate with the risks encountered, and includes processes such as developing procedures for assessing the risk, the actions that need to be taken for different levels of risk, and the methods that correct or prevent the problem from recurring.

FDA notes that, as more fully set forth in section V.D., FDA utilizes many of the definitions in ISO 13485 and ISO 9000 to harmonize the QMSR to the greatest extent possible with ISO 13485 and to reduce the potential for misinterpretation of the QMSR requirements.

(Comment 21) Commenters noted that ISO 13485 is a copyrighted document that may be associated with a fee and thus may not be accessible to all entities, and suggested that FDA make the standard available and cost-free.

(Response) FDA agrees with the portion of the comment that notes that ISO 13485 is a copyrighted document but advises that a mechanism exists to enable any entity to access ISO 13485 and ISO 9000 through the ANSI Standards Incorporated By Reference portal. The website for the portal is located at *https://ibr.ansi.org/Standards/iso.aspx.* Utilizing the web address will give the user access to a read-only version of ISO 13485 and Clause 3 of ISO 9000, at no cost to the user. As noted, the definitions set forth in ISO 9000 are also available to users at no cost at *https://www.iso.org/obp/ui#iso:std:iso:9000:ed-4:v1:en.*

D. Definitions

(Comment 22) One comment opined that because ISO 13485 sets forth its own definitions, the Agency does not have the authority to promulgate definitions that differ from ISO 13485.

(Response) FDA disagrees with the comment. FDA's legal authority to promulgate the QMSR derives from its statutory authority, more fully set forth above, at section IV. That legal authority includes the ability to retain and modify regulatory definitions in the QMSR, as appropriate. In addition, ISO 13485 itself anticipates that each jurisdiction may have its own definitions (see ISO 13485, at Clause 0.1). FDA also notes that there are, however, certain definitions in ISO 13485 that FDA cannot adopt because they conflict with or differ from definitions established in the FD&C Act or by regulations in other parts in Title 21 of the CFR.

(Comment 23) One comment asked FDA to clarify its expectations regarding how manufacturers should update their existing quality management systems to ensure that all terms, definitions, and documentation are consistent with the new QMSR. The commenter asked that FDA provide guidance for how organizations are to update their QMS.

(Response) Because each organization's QMS is unique to its operations, FDA is not able to provide advice about how each organization should evaluate its existing QMS for consistency with the QMSR. Similarly, FDA is not able provide advice on how to revise specific documents or otherwise update an existing QMS within an organization.

(Comment 24) Some comments recommended that FDA fully align the QMSR's definitions with those in ISO 13485. Other comments suggested FDA clarify how terms in ISO 9000 function in the QMSR. Multiple commenters also

asked FDA to clarify where there are similarities and differences between definitions in the former QS regulation, the QMSR, ISO 13485, and ISO 9000.

(Response) FDA partially agrees with the suggestion that FDA more fully align the definitions in the QMSR with the definitions in ISO 13485 and has modified the proposed § 820.3 in response. There are, however, certain definitions in ISO 13485 that FDA cannot adopt because they either conflict with or differ from definitions established in the FD&C Act or its implementing regulations in other parts in Title 21 of the CFR (see § 820.3(b)).

ISO 13485 uses ISO 9000 as a normative reference and Clause 3 of ISO 13485 states that for the purposes of ISO 13485, ''the terms and definitions in ISO 9000 apply.'' In this rulemaking, except as specified in § 820.3, we take the same approach. This will help harmonize the QMSR to the greatest extent possible with ISO 13485 and to reduce the potential for misinterpretation of the QMSR requirements.

FDA acknowledges that some terms that appeared in the former QS regulation no longer appear in the QMSR. FDA further acknowledges that certain terms that appear in the QMSR do not appear in ISO 13485, and thus are not defined in that document. While we have not provided comparisons between all definitions in the QMSR and the QS regulation or ISO 13485, subsequent responses in this section address specific terms for which we received questions. Finally, although ISO 13485, the QMSR, and the former QS regulation use some different terms, the requirements remain substantially the same.

As discussed previously, FDA considers the terms and definitions in ISO 9000, as used in ISO 13485, to be incorporated by reference into the QMSR except for those terms and definitions FDA has determined are necessary to define in § 820.3 to satisfy requirements within the FD&C Act or its implementing regulations. This includes the corresponding notes for terms defined in ISO 9000, and as stated previously, FDA considers these notes as providing important context for understanding and implementing the standard rather than setting forth regulatory requirements. By incorporating these terms and definitions by reference, FDA intends to minimize the regulatory burden on device manufacturers, which will allow for a harmonized application of the ISO 13485 standard across regulatory jurisdictions to the extent permissible by, and consistent with, the FD&C Act. FDA reiterates that it does not intend to incorporate any definitions for terms that are inconsistent with definitions set forth in the FD&C Act.

We also note that ISO 13485 only references the terms and definitions in Clause 3 of ISO 9000, which are being incorporated by reference here, and does not reference the remainder of the document; FDA considers the remainder of ISO 9000 to fall outside the scope of the QMSR. Organizations may choose to incorporate concepts, processes, or other aspects of ISO 9000 into their organization's QS and, so long as the resultant system is compliant with the QMSR established in this rulemaking, we do not take a position here on those choices. For additional details on specific terms, please see the discussions below in responses to comments 26 through 30.

(Comment 25) One comment suggested that because FDA proposed to include definitions in the QMSR that are different from those in ISO 13485, the QMSR has created a second, alternate standard with which manufacturers would need to comply.

(Response) FDA disagrees that we are creating a second, alternate standard. Rather the QMSR must be consistent with the FD&C Act and its implementing regulations and, as noted throughout this rulemaking, any differences between the QMSR and the ISO 13485 are intended to help manufacturers satisfy requirements within the FD&C Act and its implementing regulations. FDA has added limited additional requirements to the QMSR where appropriate, and device manufacturers must meet those requirements in addition to those set forth in ISO 13485 (see *e.g.,* §§ 820.10 through 820.45). Additionally, in response to other comments FDA has adopted, to the extent possible, the definitions used in ISO 13485 in this rulemaking, the extent of potential differences between the QMSR and ISO 13485 has been reduced compared to the proposed rule.

(Comment 26) Many comments recommended that FDA revise its proposed definitions for specific terms. Some comments recommended that FDA adopt the definitions set forth in ISO 9000 for the terms ''customer,'' ''nonconformity,'' and ''verification.'' Multiple comments noted that because these terms are defined in ISO 9000, FDA can adopt those definitions for the QMSR, and does not need to create new definitions in this rulemaking.

(Response) FDA agrees with these comments and has adopted for the final QMSR the definitions set forth in ISO 9000, including the terms ''customer,'' ''nonconformity,'' and ''verification.'' With respect to the definition for ''customer,'' we note that when considering the requirements related to customer property in Clause 7.5.10, manufacturers must comply with this provision to the extent necessary to assure the safety and effectiveness of the devices being manufactured, consistent with the requirements of section 520(f) of the FD&C Act. For example, a manufacturer is expected to ensure that the integrity of a component provided by a contract manufacturer is not compromised before it is incorporated into the device being manufactured. To the extent any customer property requirements may be interpreted to go beyond the safety and effectiveness of the devices being manufactured, FDA does not intend to enforce this provision for such activities.

(Comment 27) Multiple commenters recommended that, to harmonize with ISO 13485 and to avoid redundancy, FDA should either adopt the definition of ''top management'' from ISO 9000, or retain both the term ''management with executive responsibility'' and the definition of that term from § 820.3(n) of the QS regulation. One commenter suggested that the term ''management with executive responsibility'' conveys the intent of the term more clearly than the definition set forth in ISO 13485.

(Response) FDA agrees with the comments recommending FDA avoid redundancy and harmonize with the standard and further agrees that the QMSR should utilize the definition set forth in ISO 9000 for the term ''top management.'' FDA disagrees with those comments that suggested FDA retain either the term ''management with executive responsibility'' or its definition from the QS regulation. Utilizing the definition in ISO 9000 for the term ''top management'' does not change that FDA expects medical device manufacturers, led by individuals with executive responsibilities, to embrace a culture of quality as a key component in ensuring the manufacture of safe and effective medical devices that otherwise comply with the FD&C Act.

A culture of quality meets regulatory requirements through a set of behaviors, attitudes, activities, and processes. Top management ensures that applicable regulatory requirements are met through the integration of QMS processes. For example, quality cannot be inspected or tested into products or services. Rather, the quality of a product or service is established during the design of that product or service, and achieved through proper control of the manufacture of that product or the performance of the service. Because FDA is incorporating the definition of

''top management,'' it is, therefore, unnecessary to retain the definition of ''management with executive responsibility'' in the QS regulation.

(Comment 28) Multiple comments noted that FDA's proposed definition of the term ''product'' differed from the definition in ISO 13485 and recommended either adopting the definition from ISO 13485, or using an alternative definition than the one proposed by FDA.

(Response) FDA agrees with the comments recommending that it adopt the definition set forth in ISO 13485 for the term ''product.'' FDA disagrees with those comments that suggested an alternate definition for the term, as FDA considers the definition in ISO 13485 to be appropriate, and an alternate definition would not further the goal of harmonizing device CGMP requirements to the extent possible. Further, establishing other definitions would not serve the purpose of this rulemaking; *i.e.,* harmonization with ISO 13485. We note, in adopting ISO 13485's definition of ''product,'' that we consider this definition to include, but it is not limited to, components, in-process devices, finished devices, services, and returned devices. For example, services may be parts of the manufacturing or quality system that are contracted to others, such as, plating of metals, testing, consulting, and sterilizing, among other services.

(Comment 29) One comment noted that the terms ''correction,'' ''corrective action,'' and ''preventive action,'' although defined in ISO 9000 and important for use in ISO 13485, were not addressed in the proposed rule, and asked FDA to introduce definitions for these terms in the final QMSR.

(Response) FDA agrees that the proposed rule did not address the terms ''correction,'' ''corrective action,'' and ''preventive action.'' This final rule provides that the definitions set forth in ISO 9000 apply for the terms ''correction,'' ''corrective action,'' and ''preventive action.'' FDA considers part 806 (21 CFR part 806) to apply to manufacturers who conduct corrections or take corrective actions that occur after the product is released. Additionally, ''correction'' may also refer to scrap, repair, rework, or adjustment and relates to eliminating a nonconformity, whereas ''corrective action'' relates to the elimination of the cause of nonconformity and to prevent recurrence. FDA clarifies that consistent with the former QS regulation, as part of an effective quality system, manufacturers must verify or validate corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device.

After consideration, we have included in § 820.3 one definition for ''batch'' or ''lot'' consistent with the definition of these terms in § 820.3(m) of the QS regulation. We note that these terms are utilized in ISO 13485 and are not defined there or in ISO 9000. We consider maintaining the definition of these terms to be important for implementing a QMS consistent with this rule. Additionally, in keeping with FDA's intent to align terminology more fully in the QMSR with ISO 13485, we have decided not to finalize the proposed definitions for the terms ''process validation,'' and ''design validation.'' These terms are not defined in either ISO 13485 or ISO 9000, and FDA considers definitions for these terms to be unnecessary because the concepts and intents underlying these terms are encompassed by other terms as used in the standards, including but not limited to ''process,'' ''validation,'' and ''design and development.''

(Comment 30) Many comments asked that FDA retain the term ''establish'' in the QMSR. Commenters noted that the QS regulation defined the term ''establish'' to mean ''to define, document, and implement,'' and comments suggested that retaining that definition would provide continuity between the QS regulation and the new QMSR and would help provide clarity regarding an organization's responsibilities under the QMSR. Some comments opined that the term ''document'' as utilized in ISO 13485 does not have the same meaning as the term ''establish'' used in the QS regulation.

(Response) FDA disagrees with these comments and affirms that retaining the previous definition of the term ''establish'' is not necessary in this rulemaking. FDA agrees that the terms ''document'' in ISO 13485 and ''establish'' in the QS regulation do not have the same meaning, and it was not FDA's intention to replace the term ''establish'' with ''document.'' Clause 0.2 in ISO 13485 clarifies that ''document'' encompasses the activities of establishing, implementing, and maintaining. FDA considers the term ''document'' as used in ISO 13485 to be appropriate for implementation of the QMSR and has determined that retaining a separate definition for ''establish'' in § 820.3 would be redundant, could lead to confusion, and would unnecessarily increase the potential for misinterpretation and apparent conflicts with QMS requirements in other regulatory jurisdictions.

(Comment 31) Some comments noted that the terms ''device master record'' (DMR), ''design history file'' (DHF), and ''device history record'' (DHR) do not appear in ISO 13485 and were not separately defined in the proposed rule and asked FDA to clarify whether those terms remain part of this rulemaking. Commenters observed that the term DMR is used in the previous QS regulation, but does not appear in the QMSR. Commenters did not agree that the concepts included in the previous term DMR are adequately covered under the requirements for a medical device file (MDF), discussed in Clause 4.2.3 of ISO 13485. One commenter asked that FDA provide a direct comparison of the terms DMR and MDF, multiple commenters suggested that the proposed definitions would further confuse expectations, and multiple commenters suggested that the term DMR has a long history of use and is not interchangeable with the term MDF. For these reasons, commenters opined that it would be unnecessarily burdensome and complicated for organizations to update their existing QMS to comply with the term ''medical device file.''

(Response) FDA agrees with the comments to the extent that they correctly identify that ISO 13485 does not contain requirements for record types specified in the QS regulation, such as quality system record (QSR), DMR, DHF, and DHR. As stated in the QMSR proposed rule, we are not retaining separate requirements for these record types in the QMSR and have eliminated terms associated with these specific record types because we believe the elements that comprise those records are largely required to be documented by ISO 13485, including Clause 4.2 and its subclauses, and Clause 7 and its subclauses. For example, many of the requirements previously in the DHR are largely required to be in the medical device or batch record, as described in Clause 7.5.1.

Similarly, consistent with the former DHF, Clause 7.3.10 requires the design and development file to contain or reference all the records necessary to establish compliance with design and development requirements, including the design and development plan and design and development procedures.

Clause 4.2.3 requires that the MDF will contain or reference the procedures and specifications that are current on the manufacturing floor. The final design output from the design phase, which is maintained or referenced in the design and development file, forms the basis or starting point for the MDF. Previously, product specifications,

procedures for manufacturing, measuring, monitoring, and servicing, and requirements for installation were included in a manufacturer's DMR and will now be located in the manufacturer's MDF.

The recordkeeping requirements in ISO 13485 are substantively similar to those in the QS regulation and, because there is no reference to these terms in ISO 13485, we have eliminated this terminology as it is no longer necessary. Retaining the definition of the DMR in the QMSR would, therefore, be redundant and could lead to confusion and misinterpretation of the requirements of the QMSR.

FDA disagrees that compliance with the concept of a MDF in the QMSR will be overly burdensome as we expect the burden to be similar to requirements associated with record types in the QS regulation. It is important to ensure that records and documentation are maintained to meet the requirements of the QMSR for each organization, and recognizes that each organization will implement a QMS specific to its requirements regarding device safety and effectiveness, including with respect to records and documentation.

(Comment 32) FDA received one comment recommending that FDA expand the definition of ''risk'' to encompass both the concept of regulatory obligations and the consequences of failure to meet those obligations, as the commenter suggested that the definition set forth in ISO 13485 was insufficient without that language.

(Response) FDA disagrees partially with this comment and considers the definition of the term ''risk'' as utilized by ISO 13485 to be appropriate. FDA agrees with the commenter that organizations involved in the life cycle of a medical device must comply with the appropriate regulatory requirements and responsibilities. To the extent that these regulatory requirements intersect with an organization's QMS, we agree that the QMS should address those requirements. In addition, ISO 13485 Clause 0.2 states that ''when the term 'risk' is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.'' For these reasons, we do not believe that a definition for ''risk'' unique to the QMSR is necessary and are retaining the unmodified definition in ISO 13485.

(Comment 33) FDA received multiple comments asking FDA to clarify the term ''component.'' Some comments recommended that FDA specify that a component that meets the definition of a device in section 201(h) of the FD&C Act is subject to the applicable provisions of the QMSR. Other comments asked FDA to identify the circumstances under which a component of a medical device would be subject to the requirements of the QMSR. Some comments requested additional clarification on the differences between a component and an accessory or a raw material.

(Response) FDA disagrees with the comments suggesting that FDA modify the definition of the term ''component.'' The definition of the term is unchanged from the definition used in the QS regulation, and we note that a raw material is already explicitly included within this definition; that is, a ''raw material'' may be a ''component'' of a finished medical device for the purposes of the QMSR. FDA considers an accessory, on the other hand, to be itself a finished device in this rulemaking. See Comment 34 for additional discussion of the term ''accessory.''

To distinguish raw material and components from ''finished devices,'' FDA notes that finished devices are all devices that are capable of functioning, including those devices that could be used even though they are not yet in their final form. For example, devices that have been manufactured or assembled, and need only to be sterilized, polished, inspected and tested, or packaged or labeled by a purchaser/manufacturer are clearly not components but are now in a condition in which they could be used, therefore meeting the definition of a ''finished device.''

Additionally, the distinction between ''components'' and ''finished devices'' was not intended to permit manufacturers to manufacture devices without complying with CGMP requirements by claiming that other functions, such as sterilization, incoming inspection (where sold for subsequent minor polishing, sterilization, or packaging), or insertion of software, will take place. The public would not be adequately protected in such cases if a manufacturer could claim that a device was not a ''finished'' device subject to the CGMP regulation because it was not in its ''final'' form. We also note that it is not necessary for a device to be in commercial distribution to be considered a ''finished device.''

The scope of the QMSR is the same as the QS regulation and explicitly applies to manufacturers of medical devices and requires that manufacturers of finished devices apply an ongoing risk-informed assessment of suppliers to ensure the provision of quality products or services, including related to components. As stated in the proposed rule, FDA's intent is to harmonize medical device CGMP requirements while maintaining consistency with our statutory and regulatory framework. Manufacturers must clearly document the type and extent of control they intend to apply to products and services. Thus, a finished device manufacturer may choose to provide greater in-house controls to ensure that products and services meet requirements or may require the supplier to adopt measures necessary to ensure acceptability, as appropriate.

FDA generally believes that an appropriate mix of supplier and manufacturer quality controls are necessary. However, finished device manufacturers who conduct product quality control solely in-house must also assess the capability of suppliers to provide acceptable product. Where audits are not practical, this may be done through, among other means, reviewing historical data, monitoring and trending, and inspection and testing. FDA further notes that certification may not provide adequate assurances of supplier quality without further evaluation. Just as with the QS regulation, the provisions of the QMSR do not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to consider provisions of this regulation as appropriate.

(Comment 34) One comment asked that FDA include a definition for the term ''accessory'' in the QMSR.

(Response) FDA disagrees that it is appropriate to define the term ''accessory'' in the QMSR, because a medical device is subject to the requirements of the QMSR whether or not it is an ''accessory.'' The term ''device'' as defined in section 201(h)(1) of the FD&C Act includes ''any component, part, or accessory.'' See Comment 33.

In this rulemaking, FDA considers an accessory to be a finished device. That determination is consistent with the FD&C Act, its implementing regulations, and FDA's guidance discussing classification pathways for accessories under section 513(f)(6) of the FD&C Act (21 U.S.C. 360c(f)(6)) (Ref. 13). For example, FDA considers an accessory to be a finished device for purposes of classifying a device under section 513 of the FD&C Act. Further, in conducting such a classification analysis, FDA has stated that it considers an accessory to be a finished device that is intended to support, supplement, and/or augment the performance of one or more other

devices. While distinguishing whether a device is an accessory is helpful for identifying potential classification mechanisms under section 513 of the FD&C Act, FDA considers it immaterial to whether an accessory is subject to the provisions of the QMSR because accessories are finished devices and are therefore subject to the provisions of the QMSR.

(Comment 35) One comment addressed the use of the term ''record'' in the proposed rule. The commenter seemed to interpret that ''record'' could mean either procedures or quality activity results depending on the section of the QS regulation. The comment considered the proposed rule for the QMSR to properly use the term ''record.'' The commenter also noted that within the family of ISO standards, ''document'' and ''record'' have distinct meanings.

(Response) FDA partially agrees with the comment to the extent that it supports FDA's use of the term ''record'' within the QMSR, as described in the proposed rule. FDA also agrees that there is a clear distinction between the terms ''document'' and ''record'' in ISO 13485 and the relevant portion of ISO 9000. Clause 4.2.4 of ISO 13485 specifies that documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.5. FDA adds that the term ''specification'' is also a distinct term. For example, a record and a specification are types of documents as defined in ISO 9000.

Because this comment is supportive of FDA's proposed use of these definitions in the QMSR, we have determined that revisions to the relevant portions of the rule are not necessary.

(Comment 36) One comment noted that in ISO 13485, the definition of the term ''distributor'' appeared to the commenter to be broader than the definition of the term in part 803 (21 CFR part 803). In particular, the commenter understood the term ''distributor'' as defined in part 803 not to include retailers, in contrast to the definition in ISO 13485, which does.

(Response) FDA recognizes that the definitions for the term ''distributor'' used in ISO 13485 and 21 CFR 803.3(e) are not identical, and that the definition of ''distributor'' in the QMSR may include retailers, as retailers further the availability of a medical device to the end user, per the definition in ISO 13485. We note that FDA intends to evaluate a firm's conformity to the requirements of the QMSR related to distribution through the initial consignee. ISO 13485 requires entities to develop and maintain a quality management system appropriate for the activities of the organization, including the requirements relevant to distribution (see ISO 13485, Clause 3.5). The regulation at part 803, by contrast, establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors.

Although terminology may differ, the requirements that are applicable to distributors in the QMSR and the requirements that apply to distributors under part 803 are appropriate for their purposes. We do not consider there to be conflict between the two and do not expect confusion regarding interpretation of the requirements under these respective provisions. We are therefore retaining the definition of ''distributor'' as written in ISO 13485 for the purposes of compliance with the QMSR, which additionally will help accomplish the goal of harmonization. Similarly, in this rulemaking, we are not amending the definition of ''distributor'' in part 803 for the purposes of compliance with that part.

(Comment 37) One comment suggested that including definitions for the terms ''labeling'' and ''marketing'' would help clarify when promotional materials for a product are considered labeling.

(Response) FDA disagrees that definitions for the terms ''labeling'' and ''marketing'' should be included in the QMSR. The FD&C Act defines the terms ''label'' and ''labeling'' in section 201(k) and (m) of the FD&C Act, respectively, and we consider it unnecessary and redundant to include those definitions in the QMSR. The term ''advertising'' is used throughout the FD&C Act and encompasses promotional materials (*e.g.,* section 201(n), regarding information FDA may use to assess whether a device is misbranded includes an evaluation of whether ''the labeling or advertising is misleading. . . .''). For the purposes of compliance with the QMSR, a separate definition for ''marketing'' is unnecessary, as marketing is not addressed in ISO 13485.

(Comment 38) Two comments suggested that replacing the term ''manufacturing material'' in the QS regulation with ''process agent'' in the QMSR would create a conflict with ISO 13485. These comments seemed to interpret Clause 7.5.2 of ISO 13485 to require that process agents be removed from the product during manufacture, but that the definition for ''process agent'' in the QMSR suggests that the process agent may be ''present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.''

(Response) FDA partially disagrees with this comment because it misinterprets Clause 7.5.2 of ISO 13485. In particular, Clause 7.5.2 of ISO 134385 does not require that process agents are to be removed from all products. This Clause discusses ''cleanliness of product'' within the context of ''production and service provision'' and states that in certain cases, the organization ''shall document requirements for cleanliness of product or contamination control of product.'' Section (e) of the Clause states that when ''process agents are to be removed from product during manufacture'' such documentation requirements apply. FDA expects removal of a process agent if it is reasonably expected to have an effect on product quality. The process agent should be removed or limited to an amount that does not adversely affect the device quality. To further clarify our position, process agents must be assessed, found acceptable for use, and controlled in a manner that is commensurate with their risk. Further, we note that a process agent is a ''product'' as defined in ISO 13485, consistent with note 1 in the definition for the term ''product,'' which explains that ''processed materials'' are one of four generic product categories.

Although we do not consider the proposed definition for ''process agent'' in the QMSR to conflict with the use of the term ''manufacturing material'' in the QSR, we have determined that it is not necessary to finalize the separate definition for ''process agent.'' In an effort to harmonize with ISO 13485 to the fullest extent possible, we are not finalizing certain FDA-specific definitions for terms in the QMSR where the terms are consistent with our existing regulatory and statutory framework (see response to Comments 24 and 26 through 29).

(Comment 39) Some comments asked that FDA incorporate the definition for ''rework'' found in ISO 9000 and asked for clarification on FDA's intended interpretation of the term within the context of the medical device life cycle.

(Response) FDA disagrees with this comment. FDA is not adopting the definition of rework in ISO 9000 and has determined that is important to finalize the proposed definition of ''rework'' in § 820.3 for consistency with our existing statutory and regulatory framework for postmarket monitoring and reports, including those governing corrections, repairs, removals, and recalls (see sections 518 and 519(g) of the FD&C Act (21 U.S.C. 360h and

360i(g)), and 21 CFR parts 7, 806, and 810. In particular, FDA considers it important that the definition make clear that actions taken by an organization on a nonconforming product after a device has been released for distribution should not be considered a type of rework, as the existing statutory and regulatory requirements, and this final rule, consider rework to be action(s) taken before the device is released for distribution, and not after distribution. This distinction is not addressed by the definition of ''rework'' in ISO 9000.

(Comment 40) A comment suggested that the QMSR should include a definition for the term ''critical supplier'' as that term is defined and used in MDSAP.

(Response) FDA disagrees with this comment and does not consider a definition of the term ''critical supplier'' to be needed in the QMSR. We acknowledge that purchased products and the suppliers of those products can be critical to ensuring safety and effectiveness throughout a medical device's life cycle. The QMSR describes a process of continuous evaluation to address products and suppliers. Clause 7.4 of ISO 13485 specifies that an organization must evaluate suppliers of purchased products in terms of ability and performance of the supplier, commensurate with the ''effect of the purchased product on the quality of'' the final finished device and in terms of the ''proportionate risk associated with'' the final finished device. Additionally, monitoring and reevaluation of suppliers and the performance of purchased products is required. Because ISO 13485 already requires quality- and risk-focused continuous evaluation of all purchased products and suppliers, FDA has concluded that an additional definition of ''critical supplier'' would be redundant and is not necessary for this rulemaking. FDA notes that a consultant may supply advice and/or information to a firm (*i.e.,* a service) and the QMSR requires that a manufacturer determine what it needs to adequately carry out the requirements of the regulation and to assess whether the consultant can adequately meet those needs.

(Comment 41) One comment suggested that § 820.15, Clarification of Concepts, in the proposed rule is unnecessary and should instead be incorporated into § 820.3.

(Response) FDA agrees with this comment and has revised the rule to remove § 820.15 and move the clarification of certain concepts and terms to § 820.3(b). Because the information in this section is intended to help clarify how terms in the QMSR should be interpreted, we consider this section to have a similar intent to that of the definitions provision. We also think that combining these sections should help improve readability and ease interpretation of the overall QMSR. See section V.F for additional discussion of comments received regarding § 820.15 of the proposed rule.

E. Requirement for a Quality Management System

(Comment 42) FDA received multiple comments regarding proposed § 820.10(b), which requires that manufacturers establish and maintain a quality management system and comply, as appropriate with the other ''applicable regulatory requirements'' including, but not limited to, those requirements listed in the codified. One comment asked that FDA list the other sections of ISO 13485 that apply to medical device manufacturers, for the purposes of complying with § 820.10. Another comment asked FDA to clarify whether parts 803 and 806 remain applicable to device manufacturers after this rulemaking.

(Response) There are many portions of ISO 13485 that refer to ''applicable regulatory requirements.'' We have included FDA requirements that are relevant to the phrase ''applicable regulatory requirements'' to assist manufacturers in understanding how ISO 13485 relates to other regulatory requirements for devices. We have identified certain instances of the phrase ''applicable regulatory requirements,'' and therefore, the list is not intended to be comprehensive. Regulated manufacturers are responsible for identifying and meeting all applicable requirements, even if such requirements are not specifically called out in § 820.10.

To the extent the comment is asking what sections of ISO 13485 apply to device manufacturers, FDA notes that all sections of ISO 13485 apply to device manufacturers. In particular, FDA considers compliance with the unique device identification (UDI) provisions of the FD&C Act to be necessary to comply with Clause 7.5.8 of ISO 13485. To comply with Clause 7.5.9.1, a manufacturer is required to document procedures for traceability in accordance with the requirements of part 821 (21 CFR part 821) if that provision is applicable. Also, to comply with Clause 8.2.3 of ISO 13485, manufacturers are required to notify FDA of complaints that meet the reporting criteria of part 803. And, to comply with Clauses 7.2.3, 8.2.3, and 8.3.3 of ISO 13485, this rulemaking requires manufacturers to handle advisory notices in accordance with the requirements of part 806. Because parts 803, 806, 821, and 830 are particularly relevant to meeting the requirements set forth in the ISO 13485 Clauses listed in § 820.10(b), FDA is not making any changes to the listed requirements.

The QMSR also allows for flexibility such that if a manufacturer engages in only some operations subject to the requirements of the QMSR but not in others, the QMSR allows organizations to identify and document the requirements of the QMSR that are not applicable to that organization. FDA recognizes, however, that organizations are seeking guidance and clarification on FDA's expectations regarding an organization's implementation of, and compliance with, the QMSR. To help facilitate understanding, FDA is in the process of evaluating its existing policies, procedures, and guidance for industry to be consistent with the QMSR.

(Comment 43) A comment implied that specific sections of proposed § 820.10(b)(1) through (3) were not needed for several reasons, including that:

- the requirements in proposed § 820.10(b)(1) are already addressed by § 820.3(cc) of the QS regulation and by reference to part 830,
- the requirements in proposed § 820.10(b)(2) are already addressed by § 820.65 (21 CFR 820.65) of the QS regulation and by part 821, and
- the requirements in proposed § 820.10(b)(3) are already addressed by § 820.198(a)(3) (21 CFR 820.198(a)) of the QS regulation and part 803.

(Response) FDA disagrees that § 820.10(b)(1) through (3) are not needed, because FDA is removing the majority of requirements in the QS regulation previously in part 820 and is revising the remainder of the part to harmonize with FDA's statutory and regulatory framework. Sections 820.3(cc), 820.65, and 820.198(a)(3) of the QS regulation have been withdrawn, and the new QMSR no longer includes these provisions.

The requirements enumerated in the new § 820.10(b)(1) through (3) make explicit that compliance with other parts of Title 21 is central to a comprehensive QMS system. Further, they are necessary because ISO 13485 directs the manufacturer to follow ''applicable regulatory requirements.'' We have included FDA requirements that are relevant to the phrase ''applicable regulatory requirements,'' to assist manufacturers in understanding how ISO 13485 relates to other regulatory requirements for devices. We have only identified certain instances of

the phrase ''applicable regulatory requirements,'' and therefore, the list is not intended to be comprehensive. Regulated manufacturers are responsible for identifying and meeting all applicable requirements, even if such requirements are not specifically listed in § 820.10.

(Comment 44) FDA received comments asking that FDA remove the reference to Clause 7.5.8 of ISO 13485 in the proposed § 820.10(b)(1). One commenter suggested that the reference to Clause 7.5.8 seemed to require that organizations assign a UDI to products throughout the product development cycle, while part 830 only requires UDI for finished devices. This comment also asked that FDA remove the reference to part 821 in the proposed § 820.10(b)(2) because the reference to part 821 is confusing, as the commenter opined that traceability requirements in Clause 7.5.9.1 are not the same as the requirements for device tracking under part 821.

(Response) FDA disagrees with the comment's interpretation of the regulations, and takes this opportunity to clarify its expectations regarding compliance with parts 830 and 821 for the purposes of the QMSR. First, we note that Clause 7.5.8 of ISO 13485 requires that as part of its QMS, an organization must document a process for product identification and, if required by applicable regulatory requirements, must document a system to assign UDI. The QMSR clarifies the applicable regulatory requirements for UDI in § 820.10(b)(1), which states that the system for assigning UDIs must comply with part 830. The QMSR, therefore, requires that an organization document a process to identify a product by ''suitable means throughout product realization'' and also that an organization document a system to adequately identify devices through distribution and use, consistent with part 830. In light of those provisions, FDA does not consider the QMSR to require an organization to assign a UDI to devices under development because the provisions in part 830 apply to a device in commercial distribution. Similarly, FDA does not take a position in this rulemaking on whether an organization should incorporate UDI as part of its documented process for identification of devices that are not in commercial distribution, so long as the requirements of the QMSR are met.

FDA also disagrees with the portion of the comment addressing compliance with § 820.10(b)(2). FDA does not consider the reference to part 821 to create a general requirement that an organization's traceability procedures adhere to the requirements of part 821. Rather, this reference makes explicit that when a device is subject to the requirements of part 821, an organization shall, among other things, document procedures for those requirements in its QMS in accordance with Clause 7.5.9 of ISO 13485.

(Comment 45) FDA received multiple comments regarding proposed § 820.10(c) Design and Development. In the preamble to the proposed rule, FDA proposed to clarify that Clause 7.3 Design and Development of ISO 13485 applies only to the manufacturers of the class I devices that are listed in § 820.10(c) in addition to all manufacturers of class II and III devices. Multiple commenters asked FDA to clarify this concept and to remove the word ''only'' to avoid the potential for confusion regarding to which devices this provision applies. One comment stated that under ISO 13485 a manufacturer of any type of class I device needs to follow design controls and that FDA's exclusion of most class I devices differs from ISO 13485. One comment asked FDA to clarify whether class I devices that are constituent parts of combination products will be subject to design and development requirements.

(Response) FDA appreciates the numerous questions regarding the scope of the QMSR with respect to design and development. The QMSR, as proposed, retains the scope of the previous § 820.30(a) of the QS regulation and does not modify which devices are subject to these requirements. Manufacturers of class II and class III, and certain class I devices described in § 820.10(c) must comply with the requirements in Design and Development, Clause 7.3 and its subclauses in ISO 13485. We further note that the device and development requirements, like other QMSR requirements, apply to all finished devices, including devices licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) (*e.g.,* in vitro diagnostic devices that are intended for blood donor screening and compatibility testing). FDA understands the comments recommending the removal of the term ''only'' from the preamble of the proposed rule explaining that Clause 7.3 Design and Development of ISO 13485 applies to the manufacturers of the class I devices that are listed in § 820.10(c) in addition to all manufacturers of class II and class III devices.

FDA disagrees with the comment asserting that FDA's decision to limit the applicability of the design and development requirements to a subset of class I devices is inconsistent with ISO 13485. To the extent that ISO 13485 addresses how the standard may be applied in a particular regulatory jurisdiction, the standard explicitly defers to those jurisdictions. Specifically, § 820.10(c) is consistent with clause 1 of ISO 13485, which recognizes that there may be exclusions by the regulatory authority from the Design and Development requirement and directs the manufacturer to document such in its justification for exclusion. For all devices to which design and development requirements apply, FDA does not expect manufacturers to maintain records of all changes proposed during the very early stages of the design process. However, a successful QMS requires a manufacturer to document design changes made after the initial design inputs have been approved, and/or any changes made to correct design deficiencies once the design has been released to production.

To address the comment asking for clarification regarding how the requirements in § 820.10(c) apply to combination products, we note that § 4.3 (21 CFR 4.3) lists all of the CGMP regulations that may apply to a combination product, depending on the constituent parts of the product. We are not revising § 4.3 in this rulemaking, and its language and the general policies around its implementation remain unchanged. We note also that FDA has previously addressed compliance with CGMP requirements for combination products in the final rule for part 4 (78 FR 4307, January 22, 2013) and in a subsequent guidance document entitled ''Current Good Manufacturing Practice Requirements for Combination Products'', including with regard to device constituent parts that are or would be classified as class I and exempt from design and development requirements (Ref. 14).

(Comment 46) Multiple comments noted that the proposed QMSR did not appear to them to include the requirement found in the QS regulation in § 820.30(e) that each stage of design review shall include an individual(s) who does not have direct responsibility for the design stage being reviewed.

(Response) FDA agrees that the final QMSR differs from the previous QS regulation and does not include the explicit requirement that each stage of design review must include an individual(s) who does not have direct responsibility for the design stage being reviewed. We note that Clause 7.3.5 of ISO 13485 requires that design and development review include representatives of functions concerned with the stage under review as well as

other specialist personnel. FDA considers Clause 7.3.5 of ISO 13485 to provide adequate flexibility for organizations to balance management of personnel and other resources in the organization with the important contribution of independent review to the design and development process; manufacturers may to choose which individual(s) to include in each stage of design review to comply with the requirements.

FDA considers that a successful quality management system under Clause 7.3.3 and 7.3.4. will require a similar approach to design review and validation as those developed under the QS regulation. For instance, the purpose of conducting design reviews during the design phase is to ensure that the design satisfies the design input requirements for the intended use of the device and the needs of the user. Design review includes the review of design verification data to determine whether the design outputs meet functional and operational requirements, the design is compatible with components and other accessories, the safety requirements are achieved, the reliability and maintenance requirements are met, the labeling and other regulatory requirements are met, and the manufacturing, installation, and servicing requirements are compatible with the design specifications. Design reviews should be conducted at major decision points during the design phase.

For a large manufacturer, design review provides an opportunity for all those who may have an impact on the quality of the device to provide input, including manufacturing, quality assurance, purchasing, sales, and servicing divisions. While small manufacturers may not have the broad range of disciplines found in a large company, and the need to coordinate and control technical interfaces may be lessened, the principles of design review still apply. The requirements under § 820.30(e) allow small manufacturers to tailor a design review that is appropriate to their individual needs.

(Comment 47) A comment requested that FDA specify which regulatory requirements would be applicable under Clause 7.3.7 of ISO 13485, which states that as part of design and development validation, an ''organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements.''

(Response) Because the regulatory requirements that may apply to clinical evaluations are provided elsewhere, FDA declines to list such information in the codified portion of this rulemaking. Clinical studies of medical devices in the United States are generally governed by the set of regulations and requirements known as good clinical practices. These regulations apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device. The primary regulations in Title 21 that govern the conduct of clinical studies of medical devices include, but are not limited to, part 812 (21 CFR part 812), Investigational Device Exemptions; 21 CFR part 50, Protection of Human Subjects; 21 CFR part 56, Institutional Review Boards; and 21 CFR part 54, Financial Disclosure by Clinical Investigators. FDA notes that prototypes used in clinical studies involving humans may be shipped in accordance with the investigational device exemption provisions in part 812. We also note that regulations in other parts of the CFR may apply to clinical evaluation, for example those in 45 CFR part 46, Protection of Human Subjects.

(Comment 48) FDA received many comments regarding the proposed § 820.10(d) concerning traceability for implantable devices, discussed here and in the two following sets of comments and responses. This provision requires manufacturers of devices that support or sustain life to comply with the requirements in Clause 7.5.9.2 in ISO 13485. Commenters asked FDA whether the QMSR would retain § 820.65 from the QS regulation and to clarify the relationship between Clauses 7.5.9.1 and Clause 7.5.9.2 of ISO 13485 and § 820.65 and part 821 of this Title.

(Response) In response to the comment suggesting that the QMSR retain § 820.65 of the QS regulation, FDA reiterates that much of the QS regulation is being removed or amended, including § 820.65. Instead, the QMSR incorporates the traceability requirements set forth in Clause 7.5.9 of ISO 13485, including Clause 7.5.9.2, and § 820.10(d) requires that manufacturers of devices that support or sustain life comply with these traceability requirements.

(Comment 49) Comments requested that FDA reconsider the scope of § 820.10(d), suggesting that its requirements be limited to class III devices, devices that require traceability, or to implantable devices with an alternative traceability requirement developed for non-implantable devices. Some comments believed that the risks associated with devices that support or sustain life are not necessarily the same as those associated with implanted devices. Comments asked FDA to define specific terms in § 820.10(d), including the phrase ''support or sustain life,'' and to explain how firms are to determine which devices support or sustain life. One comment suggested that § 820.10(d), as drafted, could be interpreted to apply to all medical devices and recommended that FDA delete the provision to avoid confusion.

(Response) FDA considers the scope of devices subject to this provision under the final QMSR to be substantially similar to the scope in the QS regulation and declines to limit the scope of this provision in the manner suggested by the comments.

In response to the comments suggesting that it would be useful to define specific terms in § 820.10(d), FDA notes that § 820.65 of the QS regulation did not include a definition for the phrase ''support or sustain life.'' Further, it is not necessary to include a definition in the QMSR because the phrase is explained in 21 CFR part 860 and that meaning has historically been applied to CGMP requirements. Section 860.3 (21 CFR 860.3) defines the term ''life-supporting or life-sustaining device'' as ''a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.'' These meanings are helpful and well understood, and FDA does not consider additional definitions to be necessary to assess compliance with the QMSR.

We additionally note that the term ''implant'' is defined in § 860.3 as ''a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise to protect human health.'' FDA intends to consider this definition when interpreting the QMSR. To incorporate this definition more clearly into the QMSR, FDA has revised the ''clarification of concepts'' provision in § 820.3(b) to explain that the term ''implantable medical device'' as used in ISO 13485 has the same meaning as ''implant'' as described above and defined in § 860.3.

(Comment 50) Multiple comments suggested that proposed § 820.10(d) was overly burdensome. One comment stated that the requirements found in previous § 820.65 of the QS regulation were less burdensome than the requirements in ISO 13485 Clause 7.5.9.2, and another comment suggested that the perceived increased burden would itself cause devices to be less

available. A comment was concerned that this provision will increase documentation requirements and is redundant with established processes required by other testing standards and European postmarket reporting requirements. Some comments noted that it may be difficult for manufacturers to maintain records of components and to comply with these requirements for devices incorporating off the shelf technology.

(Response) We disagree that it will be overly burdensome for manufacturers to comply with this provision. The traceability requirements, and the manner in which they are applied in the QMSR, the FD&C Act, and in its implementing regulations, are substantially similar to those found in the QS regulation. For example, the requirements found in § 820.10(d) and Clause 7.5.9.2 of ISO 13485 reflect portions of the QS regulation (including 21 CFR 820.60, 820.65, 820.160, and 820.70(c)), including that a manufacturer is to establish and maintain procedures to identify devices throughout development and identify components where appropriate, to maintain distribution records, and to adequately control environmental conditions when those conditions could impact product quality.

We also have considered the comments regarding the requirement that manufacturers maintain records of components that could cause the medical device not to satisfy its specified safety and effectiveness requirements, and we consider such records to be essential to a comprehensive QMS.

Similarly, we recognize that other jurisdictions may have requirements for medical devices that are similar to those in § 820.10(d) of the QMSR, and those similarities were an important consideration in incorporating ISO 13485. We note, further, that this is consistent with our goal of harmonizing to the extent possible FDA's QMSR requirements with global standards and the requirements of other regulatory jurisdictions.

F. Clarification of Concepts

(Comment 51) FDA received comments asking FDA to clarify use of the phrases ''safety and performance'' and ''safety and effectiveness'' within the QMSR. Commenters seemed to interpret that FDA had used the two phrases interchangeably in the proposed rule and asked that FDA revise the proposed use of the phrase ''safety and performance'' because its meaning is not the same as ''safety and effectiveness.'' One commenter suggested that because the terms are different, they require different outcomes. Another commenter asked FDA to cite the source of the concept of ''safety and effectiveness.''

(Response) FDA agrees that the phrases ''safety and effectiveness'' and ''safety and performance'' are not interchangeable, and although the proposed rule explained that FDA was not proposing that the terms were interchangeable, we have nevertheless revised this rule to avoid the potential for confusion. In accordance with section 520(f) of the FD&C Act, and as stated in § 820.1, the requirements of the QMSR are intended to assure that finished devices will be safe and effective and otherwise in compliance with the FD&C Act. FDA acknowledges that ISO 13485 and the FD&C Act utilize different phrasing related to device function and use, because ISO 13485 includes criteria related to safety and performance by which to evaluate medical devices. FDA's intention is to reinforce that, despite the difference in terminology, the QMSR as a whole is intended to assure that finished devices will be manufactured to meet the statutory requirement for safety and effectiveness. The quality management system requirements specified in ISO 13485 are complementary to the technical requirements that are necessary to meet applicable regulatory requirements for safety and performance. To help clarify this position, we have revised the ''clarification of concepts'' section of the rule (proposed § 820.15, which is now included in § 820.3(b)) so that ''safety and performance'' has the meaning of ''safety and effectiveness'' only within the introduction in Clause 0.1 of ISO 13485. In the context of Clause 0.1 of ISO 13485, ''safety and performance'' means ''assessment of the performance of the device to assure the device is safe and effective'' as required by section 520(f) of the FD&C Act. The term ''safety and performance'' does not relieve a manufacturer from obligations related to ensuring that finished devices are safe and effective.

G. Supplementary Provisions

1. Control of Records (§ 820.35)

(Comment 52) Some comments noted that the requirements set forth in the QMSR, at § 820.35, appear to add additional requirements regarding control of records to ISO 13485.

(Response) FDA agrees with the comments. The QMSR includes specific and limited requirements for control of records in addition to those in ISO 13485 to ensure consistency and alignment with other requirements in the FD&C Act and its implementing regulations.

FDA considers the additional requirements specified in § 820.35 (*i.e.,* requirements that are not specified in ISO 13485) regarding control of records to be necessary to implement a QMSR that is consistent with applicable statutory and regulatory requirements. Manufacturers must meet the requirements in ISO 13485 clause 4.2.5 (any other applicable clauses of ISO 13485; for example, complaint handling shall be conducted in accordance with the requirements set forth at 8.2.2), and also meet the requirements of § 820.35. We think that these additional requirements will help ensure that records are established and maintained in a manner that is useful to FDA and manufacturers.

We have included specific requirements to ensure that the information required by part 803, Medical Device Reporting, is captured on certain records of complaints and servicing activities. We are also requiring that firms document the UDI for each medical device or batch of medical devices in accordance with part 830 in its records. Last, we are retaining the clarification from § 820.180 (21 CFR 820.180) of the former QS regulation that governs the confidentiality of records FDA receives. This reminds firms that FDA protects such records in accordance with part 20 (21 CFR part 20). As set forth in this rulemaking, manufacturers must meet the requirements in ISO 13485 Clause 4.2.5 and also meet the requirements of § 820.35.

(Comment 53) Comments noted that § 820.35 of the proposed QMSR requires that manufacturers ''obtain the signature for each individual who approved or re-approved the record.'' Many comments noted that the signature requirements described in the proposed rule appeared to apply to all records and were drafted to appear to be more stringent, and thus more burdensome, than the QS regulation. Multiple comments sought clarification on the manner and method of the signature requirement.

(Response) FDA agrees with the comments that noted that the signature requirements in the proposed rule appear to be more expansive than those in either ISO 13485 or the former QS regulation. In response to the comments and to maintain continuity with the requirements of the QS regulation and ISO 13485, FDA has revised this rule to remove the requirement that the manufacturer obtain the signature for each individual who approved or reapproved the record, and the date of such approval on the record.

FDA notes that where ISO 13485 uses the term ''approved,'' that term means that an approved document, or certain record of a type that requires approval by ISO 13485, has a signature and date. Additionally, we note that FDA will consider signatures that utilize the method the Agency determines fulfills electronic signature requirements to be compliant with this requirement. Manufacturers can choose to develop electronic records and electronic methods for denoting approval. Our focus is on whether the substance of the requirements is met and not the physicality of the record or signature methodology.

(Comment 54) Commenters requested that FDA elaborate on the specific requirements for maintaining complaint records, records of servicing, and for documenting UDI. Some commenters noted that proposed § 820.35(a)(4) requires that complaint records include the name and contact information of the complainant, and requested clarification regarding what information would satisfy that requirement. Other commenters suggested that an electronic address, rather than a physical address, would be appropriate on complaint records. With respect to documenting servicing records, one commenter noted that § 820.35(b)(6) requires manufacturers to record any test and inspection data that is conducted as part of the manufacturer's servicing activities and noted that manufacturers should not be required to perform such testing if it is beyond the scope of the individual servicing activity. One commenter requested that FDA clarify when the QMSR requires manufacturers to document the UDI, and another commenter asked FDA to modify § 820.35(c) to state that the UDI could be ''recorded/included'' for each medical device or batch of medical devices.

(Response) The information required by part 803, Medical Device Reporting, must appear on certain records of complaints and of servicing activities in § 820.35(a). To the extent the medical device reporting regulations permit contact information to include an electronic address, rather than a physical address, compliance with part 803 would be compliant with this rule. To provide additional clarity regarding complaint handling, we have revised § 820.35(a) to describe the circumstances under which an investigation of a complaint must be initiated and records related to that complaint must be retained. Clause 8.2.2 and § 820.35(a) require that if any complaint is not investigated, the firm shall document the reason it has not investigated that complaint. For example, if the information required for an investigation cannot be obtained, then the manufacturer must document the efforts it made to ascertain the information.

Consistent with the QS regulation, FDA expects that a firm will make a reasonable and good faith effort to obtain the information required for an investigation. Additionally, we note that if a corporation chooses to operate with different complaint handling units for products and/or establishments, the manufacturer must clearly describe and define its corporate complaint handling procedure to ensure consistency throughout the different complaint handling units. A system that would allow multiple interpretations of handling, evaluating, categorizing, investigating, and following up, would be unacceptable. Each manufacturer should establish in its procedures which one group or unit is ultimately responsible for coordinating all complaint handling functions.

FDA agrees with the comment regarding interpretation of § 820.35(b)(6) and does not consider this section to require test and inspection data for all servicing activities. Rather, when an organization's QMSR does require such test and inspection data to be generated as part of the servicing activities, those data must be included as part of the record per § 820.35(b)(6). Regarding requirements for documentation of UDI, we reaffirm our position—as stated in the proposed rule—that this rule requires that firms document the UDI for each medical device or batch of medical devices in accordance with part 830. Similarly, we disagree that the requirement in § 820.35(c) should be modified; the phrasing of this provision allows a manufacturer to comply with § 820.35(c)'s requirements in the manner appropriate for the device and its manufacturing process.

(Comment 55) FDA received numerous comments regarding the lack of an exception for management review, quality audits, and supplier audit reports, which formerly existed in the QS regulation, at § 820.180(c). Most such comments requested that FDA maintain the exceptions set forth in § 820.180(c), some suggested that FDA adopt specific language to do so, and the remainder requested that FDA clarify whether such records are exempted from inspector access. One commenter in particular noted that the current quality system inspection technique (QSIT) guide also states that management review, internal audit, and supplier audit records are exempted from inspection. Several comments expressed concern that the exception was necessary to ensure manufacturers' audit and management review reports continue to be complete and/or useful.

(Response) FDA disagrees that it should maintain the exceptions set forth at § 820.180(c). One of the primary purposes for this rulemaking effort is to move as closely as possible toward global harmonization and alignment. From a global perspective, the exceptions the comment references are not available to manufacturers being inspected by other regulators or being audited by other entities (*e.g.,* MDSAP auditing organizations), and thus, such manufacturers will not be additionally burdened by making these records available. Similarly, FDA does not consider it to be a large burden to the manufacturers who may have taken advantage of the exceptions to make these records available, as such records are maintained in the regular course of business and should be readily available. Additionally, FDA notes that its investigators have already had access to data used to inform management reviews, such as nonconformances and complaints, and any corrective actions resulting from internal and supplier audits.

FDA emphasizes that robust management review, as well as internal and supplier audit programs, are fundamental to the culture of quality discussed previously in this rulemaking and which FDA expects firms to embrace. Further, FDA intends to modify its inspectional processes consistent with this rulemaking, and does not consider this rulemaking to be the appropriate vehicle to describe any future implementation activities, including inspectional processes.

(Comment 56) One comment suggested that when ISO 13485 refers to providing evidence, FDA should allow manufacturers to determine the most appropriate type of data (qualitative or quantitative).

(Response) FDA disagrees with this comment. In this rulemaking, FDA requires that manufacturers document a quality management system that complies with ISO 13485, as modified by part 820. In general, when ISO 13485 refers to providing evidence, FDA recommends that manufacturers record quantitative data, as appropriate and commensurate with risk. Such information will assist manufacturers in monitoring the performance of their products, processes, and effectiveness of their controls. We recognize that there may be circumstances under which it is not possible or practical for an organization to generate and record appropriate quantitative data, and we consider the QMSR framework to

provide adequate flexibility to accommodate such situations in accordance with Clause 0.2 of ISO 13485.

(Comment 57) One commenter noted that in the QMSR, § 820.35(a)(6) requires manufacturers to keep a record of any corrective action and that FDA should add the term ''correction'' to the term ''corrective action,'' which FDA interprets to be parallel to the requirement in ISO 13485 at Clause 8.2.2.

(Response) FDA agrees with the commenter that adding the term ''correction'' to the term ''corrective action'' would align the QMSR with ISO 13485 and has made such modifications within § 820.35(a)(6). The QS regulation utilized the term ''corrective action,'' whereas ISO 13485 references both ''correction'' and ''corrective action.'' To harmonize with the standard, we have added the term ''correction'' to the codified for completeness. See also Comment 29.

(Comment 58) One comment inquired about how FDA interprets the requirement that records be ''readily identifiable and retrievable,'' including how FDA intends foreign manufacturers to comply with these requirements.

(Response) FDA considers this phrase to be substantially similar to the requirement in the QS regulation that records be ''reasonably accessible'' and ''readily available.'' Consistent with the QS regulation, that means that records will be made available during the course of an inspection. If the manufacturer maintains records at remote locations, records will be produced by the next working day or two, at the latest. FDA continues to believe that records can be kept at other than the inspected establishment, provided that they are made ''readily available'' for review and copying (see 61 FR 52602 at 52637). FDA considers records that a manufacturer makes available as described herein to be ''readily identifiable and retrievable.'' FDA notes that although it has made changes to revise § 820.1(c) to align with the statutory language in sections 501 and 801 of the FD&C Act, it has not changed a foreign manufacturer's obligations under this part.

2. Controls for Device Labeling and Packaging (§ 820.45)

(Comment 59) FDA interprets one comment to note that utilizing the term ''establish'' in this section creates a potential for confusion, as ISO 13485 defines the process of ''documenting'' as including the processes of ''establishing,'' ''implementing,'' and ''maintaining.''

(Response) FDA agrees with the comment, to the extent it suggests that it would be less confusing to use the term ''documenting'' in place of the phrase ''established and maintained'' in that portion of the rulemaking. FDA has made changes to the codified rule to accommodate this recommendation and notes that the clarified requirement to document includes the requirements to establish and maintain (see section V.D., Definitions).

(Comment 60) FDA received a comment suggesting that ISO 13485 fails to provide sufficient requirements for labeling and packaging, and does not address how manufacturers inspect their products' labels. The comment recommended that FDA add additional requirements to align with FDA's draft guidance document entitled ''Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff.''

(Response) FDA agrees that ISO 13485 does not specifically address the inspection of labeling by the manufacturer, which is why FDA is retaining in this rule requirements from the QS regulation that strengthen controls for labeling and packaging operations. FDA notes that many device recalls are related to labeling and packaging. Section 820.45(a) requires that manufacturers inspect their labeling and packaging for accuracy to include the requirements set forth at § 820.45(a)(1) through (5) to ensure that release of the labeling is documented in accordance with Clause 4.2.5 of ISO 13485 and so that the manufacturer ensures that labeling and packaging operations have been documented to prevent errors. Section 820.45 specifically requires that manufacturers inspect labeling and packaging before use to assure that all devices have the correct labeling and packaging, in accordance with Clause 4.2.3 and that manufacturers document that inspection.

FDA notes that in its experience, manufacturers have recalled devices where automated readers have not caught label errors. The requirement to inspect labeling and packaging does not preclude automatic readers where that process is followed by human oversight. A designated individual must examine, at a minimum, a representative sampling of all labels that have been checked by automatic readers. Further, automated readers are often programmed with only the base label and do not check specifics, such as control numbers and expiration dates, among other things, that are distinct for each label. The regulation requires that labeling be inspected for these items prior to release. FDA believes that these provisions will better assure the manufacture of safe and effective devices.

FDA disagrees that additional requirements are necessary to ensure that labeling and packaging is sufficiently addressed by this rulemaking. FDA also notes that its guidance documents set forth FDA's current thinking on a subject, but do not set forth regulatory requirements to which this rule could be aligned.

(Comment 61) One comment suggested that manufacturers subject to special controls regarding labeling and/or packaging under sections 510 and/or 513(a) of the FD&C Act may wrongly consider their devices exempt from § 820.45 because this rulemaking states that conflicting regulations that are more specific are controlling only to the extent of the conflict and also states that the generally applicable part 820 regulations apply to the extent they do not otherwise conflict with the specifically applicable regulation.

(Response) Special controls are not in conflict with the requirements of § 820.45, and thus, devices subject to special controls are subject to the requirements of § 820.45. Special controls and the labeling and packaging requirements in § 820.45 serve different purposes and are not in conflict as described in § 820.3(b). Special controls are requirements in addition to those set forth in this rulemaking and are those which FDA has determined are necessary to provide reasonable assurance of the safety and effectiveness of the device. Special controls are device-specific, and may include, among other things, special labeling requirements. Section 820.45 addresses the labeling process itself, not the content of the label (see Scope, supra).

(Comment 62) One comment recommended that FDA delete the phrase ''immediately before use'' in the requirement in § 820.45 that the manufacturer inspect the labeling and packaging immediately before use, as the commenter suggested that that phrase places an additional and new burden on manufacturers.

(Response) FDA partially agrees with the comment, and agrees that the term ''immediately'' is not necessary to accomplish FDA's goal to require manufacturers to inspect labeling and packaging to ensure that an accurate label is applied to the correct device. An effective quality system will include a process for inspecting the label for accuracy and to ensure that it is applied to the correct device before the device is distributed. FDA has made that modification in the codified text.

(Comment 63) One commenter recommended that FDA provide a definition for the term ''medical device file'' as it is used in § 820.45(c) to require that the manufacturer ensure that labeling and packaging operations have been established and maintained to, among other things, assure that all devices have correct labeling and packaging, as specified in the medical device file.

(Response) FDA disagrees that it would be appropriate and/or helpful to define the term ''medical device file'' in this rulemaking, as a definition for the term is set forth at ISO 13485 Clause 4.2.3. We note that additional discussion of the term ''medical device file'' within this rulemaking may be found in response to Comment 31.

(Comment 64) One comment recommended that FDA remove § 820.45(a)(2) through (5), as the commenter suggested that Clause 7.5.1 of ISO 13485 already establishes the need for labeling process controls, making these requirements duplicative and requiring uniformity where the commenter believed it not to be necessary.

(Response) FDA disagrees with the comment. Clause 7.5.1(e) of ISO 13485 states that ''defined operations for labelling and packaging shall be implemented.'' However, ISO 13485 fails to provide additional requirements for labeling and packaging and does not specifically address the inspection of labeling by the manufacturer. FDA is therefore retaining requirements from the QS regulation that would strengthen controls for labeling and packaging operations, given that many device recalls are related to labeling and packaging. FDA believes that these provisions will better assure the manufacture of safe and effective devices. Regulated industry must meet the requirements in ISO 13485 7.5.1 and § 820.45. Consistent with the previous QS regulation, FDA continues to expect that manufacturers will retain records of labeling operations to include the primary identification label and/labeling used for each production unit, lot, or batch record.

As stated above, we have added additional requirements to ISO 13485, which it has retained from the QS regulation, to ensure consistency and alignment with other requirements in the FD&C Act and its implementing regulations to ensure that the QMSR ensures the manufacturing of safe and effective devices. The requirements set forth at § 820.45(a)(2) through (5) are necessary to implement a QMS that is consistent with applicable FD&C Act requirements, but are not specified in ISO 13485. These requirements include the device labeling and packaging requirements, including an expiration date, storage instructions, handling instructions, and any additional processing instructions (see 21 CFR part 801).

FDA received a group of comments regarding the use of specific words in § 820.45.

(Comment 65) FDA received a group of comments regarding the use of specific words in § 820.45. One comment proposed removing the term ''distribution,'' or clarifying the term in the portion of the rulemaking that requires manufacturers to document procedures that provide a detailed description of the activities to ensure the integrity, inspection, storage, and operations for labeling and packaging, ''during the customary conditions of processing, storage, handling, distribution, and where appropriate, use of the device.'' The comment suggested that labeling generally informs users how to handle and store the product, and thus the use of the term ''distribution'' is overbroad and unnecessary.

(Response) FDA agrees that it would be useful to clarify the term ''distribution,'' but disagrees that it is appropriate to remove the term from the rulemaking. FDA will evaluate a firm's conformity to the requirements of the QMSR related to distribution through the initial consignee.

(Comment 66) The same comment suggested that FDA replace the word ''where'' with the word ''as'' in the portion of the requirement that states, ''. . . each manufacturer must establish and maintain procedures that provide a detailed description of the activities to ensure the integrity, inspection, storage, and operations for labeling and packaging, during the customary conditions of processing, storage, handling, distribution, and *where* appropriate, use of the device'' (emphasis added). The comment also asked that FDA clarify when controls (*e.g.,* inspection, storage) of labeling for use of the device would apply to the manufacturer.

(Response) FDA agrees with the suggestion, and we note that ISO 13485 uses the phrase ''as appropriate'' and clarifies how FDA interprets this phrase in clause 0.2. We have therefore changed the codified language to align with the comment, and the standard. In response to the request for additional clarification regarding which controls apply to certain activities, FDA reiterates that if a manufacturer engages in only some activities subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the activities in which it is engaged.

(Comment 67) The same comment suggested that the term ''operations'' as used in § 820.45 could refer to the application of labeling to the device as well as to the production of the label itself. The comment suggested that § 820.120(a) in the QS regulation required integrity of the label during use, where appropriate, and further suggested that the QMSR does not maintain this requirement.

(Response) FDA agrees that the term ''operations'' as used in § 820.45 can refer to both the application of labeling to the device as well as to the production of the label itself. Further, we note that § 820.45(c) provides additional clarification regarding expectations for such operations. FDA, therefore, disagrees that it is necessary to retain § 820.120(a) to maintain the requirements regarding the integrity of the label, where appropriate. As FDA has noted, we have added additional requirements to ensure consistency and alignment with other requirements in the FD&C Act and its implementing regulations. Those additional requirements are intended to ensure that the device's label contains accurate information and is attached appropriately to the device in accordance with the applicable requirements of the FD&C Act and its implementing regulations.

H. Conforming Amendments and FDA Response

(Comment 68) FDA received a comment recommending that FDA create a harmonized approach for both the QMSR and part 4 to become effective 2 years after the date of publication in the **Federal Register**.

(Response) FDA agrees with the comment and has made the recommended modifications, as set forth in the Effective Date section of this rulemaking. FDA agrees with the comment that the effective date of the revisions to part 4 and the QMSR will be the same.

(Comment 69) FDA received a comment recommending that FDA clarify how MDSAP applies to combination products.

(Response) FDA notes that at this time, combination products are outside the scope of MDSAP. In amending part 4, FDA intends to achieve consistency with the QMSR and does not intend to imply that the MDSAP program is available for combination products.

(Comment 70) Commenters recommended that the Agency clarify

whether it intends to advance the mutual recognition of pharmaceutical CGMP for combination product manufacturers that have aligned their quality management systems to § 4.4(b)(2) to meet GMP requirements for the combination products.

(Response) While FDA supports the concepts of convergence and coordination with respect to CGMPs for combination products, pharmaceutical GMPs and mutual recognition agreements for combination products are outside the scope of this rulemaking.

(Comment 71) One commenter recommended that FDA delete specific text (''upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the QMSR requirements need be made''), as the commenter suggested that the text implied that manufacturers of combination products need not comply with Clause 8.3, Clause 8.2.2, and/or Clause 8.2.3.

(Response) Compliance with the applicable provisions of the QMSR is required, and FDA disagrees that the text of the rulemaking implies otherwise. FDA agrees with the portion of the comment that recommends reiterating that manufacturers of combination products must also comply with Clause 8.2.2, and has added that provision. In addition, FDA notes that the other Clauses that the commenter lists are covered sufficiently in part 211 (21 CFR part 211). FDA notes that the language that the commenter recommends deleting previously existed in part 4.

(Comment 72) A commenter recommended that FDA add the terms ''analysis of data'' in § 4.4, as Corrective and Preventive Action has been replaced with the term ''improvement,'' and has an expanded scope. To align with ISO 13485, the commenter proposed to add the phrase ''analysis of data'' in § 4.4(b)(1)(iv).

(Response) FDA agrees with the suggestion and has added the term ''analysis of data'' to the codified text at § 4.4(b)(1)(iv) to be consistent with the phrasing in the standard.

(Comment 73) A commenter recommended that FDA align terms with parts 210 (21 CFR part 210) and 211 by modifying the definition of the term ''component'' in the QMSR consistent with the definition set forth in part 210.

(Response) FDA has considered the comment and declines to make the suggested change as we consider the term ''component'' to be appropriately defined with respect to device CGMP requirements in the QMSR and to be appropriately defined with respect to drug CGMP requirements in parts 210 and 211. FDA does not consider the definition of ''component'' set forth in § 210.3(b)(3) to be relevant to device CGMP requirements because that regulation defines the term within drug CGMP requirements. Introducing the definition in § 210.3(b)(3) in this rulemaking would lead to confusion and misinterpretation of device CGMP requirements.

(Comment 74) A commenter asked FDA to clarify whether the requirements set forth by this rulemaking will impact part 210 or part 211.

(Response) FDA clarifies that the requirements set forth by this rulemaking do not alter or change the requirements set forth at part 210 or part 211. This determination does not represent a change from the previous version of the QS regulation.

VI. Effective Date and Implementation Strategy

A. Effective Date

(Comment 75) FDA received many comments noting that the proposed effective date of 1 year was not enough time to implement this rulemaking. Some comments explained that 1 year would not be enough time to train staff, revise processes and/or procedures, and make necessary changes to current practices. Other comments explained that small firms, midsize firms, or firms who currently conduct business exclusively in the United States may need more than 1 year to become familiar with the QMSR and implement necessary changes. Several comments suggested that an effective date of 2 or 3 years after publication in the **Federal Register** would be appropriate, to allow firms adequate time to implement any such changes.

(Response) FDA has considered these comments and the testimony given during the Advisory Committee hearing. FDA agrees that firms will need to become familiar with the QMSR, and FDA appreciates that manufacturers will need to make appropriate changes within their organizations to align their QMSs, processes, and documents with the QMSR. FDA also agrees that domestic firms may find that ISO 13485 is new to them, although FDA also considers ISO 13485 to be substantially similar to the requirements of the QS regulation. Because ISO 13485 is substantially similar to the requirements of the QS regulation, FDA disagrees that small firms and/or midsize firms will need more time than larger firms to implement this rulemaking.

Therefore, to balance the concerns raised by comments and participants in the Advisory Committee Hearing and the Agency's interest in efficiently achieving global harmonization, streamlining regulatory requirements, reducing burdens on regulated industry, and providing patients more efficient access to necessary devices, FDA has reconsidered the proposed effective date of 1 year, and in this rulemaking, sets an effective date of 2 years after publication in the **Federal Register**. FDA believes 2 years is adequate time for firms to align internal processes and procedures, to make appropriate changes within their organizations, and to update their documentation with the QMSR.

(Comment 76) Some comments suggested that an appropriate effective date would be 2 years after FDA updates all guidance documents associated with this rulemaking and a subset of those comments reiterated the suggestion that FDA communicate its plan for updating associated guidance documents.

(Response) FDA disagrees with the comments. FDA does not believe guidance is needed before the effective date. For the reasons given in response to the other comments, FDA has set an effective date 2 years after publication in the **Federal Register**. FDA also disagrees with the suggestion that it is appropriate in this rulemaking to outline a schedule or plan for updating guidance documents. To help stakeholders better understand how existing policies will continue to apply within the QMSR, FDA intends to update existing guidance documents. Because we consider the QS regulation and the QMSR to be substantially similar, we expect to update guidance documents for consistency but do not expect there to be many differences in interpretation of these regulations or application of relevant policies.

(Comment 77) Some comments recommended that FDA phase in an effective date. Comments suggest that FDA either implement the effective date in phases, or allow firms to comply with either the QS regulation requirements or the requirements described in this QMSR rulemaking for a period of time following publication in the **Federal Register**. Another comment suggests that FDA use a risk-based approach to transition to the QMSR, taking into account the class of medical device.

(Response) FDA disagrees that a phased-in effective date is appropriate, because having two inspectional programs in operation at the same time would be inefficient and would result in significant potential for confusion. FDA believes that the 2-year effective date provides sufficient time to implement the QMSR, and that it meets FDA's goals

of efficiently achieving global harmonization, streamlining regulatory requirements, reducing burdens on regulated industry, and providing patients more efficient access to necessary devices. FDA recognizes that it is important for manufacturers to prepare to align their practices with the QMSR as soon as practical, and some manufacturers may choose to begin complying with the QMSR before the effective date. However, FDA does not intend to require compliance with the QMSR until its effective date. Until then, manufacturers are required to comply with the QS regulation. FDA's inspections are risk based and will continue to be consistent with section 510(h) of the FD&C Act.

B. Implementation Strategy

FDA received many comments about FDA's anticipated inspection process, and the roles of certification and participation in MDSAP following this rulemaking. FDA responds to those comments as follows:

(Comment 78) One comment suggested that FDA will need to ensure that the MDSAP audit approach reflects the QMSR and that the auditing organizations are trained accordingly.

(Response) FDA, as a participating regulatory authority in MDSAP, will evaluate the MDSAP audit approach and training needs for auditing organizations and revise as appropriate to align with the QMSR.

(Comment 79) Comments recommended that FDA expand on how it will utilize, or not utilize, certification to ISO 13485 in the MDSAP program. Commenters noted that FDA has accepted certain MDSAP audit reports—which may discuss the manufacturer's certification to ISO 13485—as a substitute for FDA inspection, and suggested that not accepting certification would create a conflict with the MDSAP inspection process. One commenter asked specifically whether FDA intends to accept an ISO certificate as a substitute for an FDA Establishment Inspection Report (EIR).

(Response) FDA agrees that it will be useful to provide additional information on the manner in which FDA intends to consider certification to ISO 13485 and how certification relates to participation in the MDSAP program. FDA notes that MDSAP is a certification program that allows for a single QMS audit based on ISO 13485 in addition to other applicable FDA device regulatory requirements, which FDA may accept in lieu of routine surveillance inspections conducted by FDA investigators.

MDSAP audits are conducted by third-party auditing organizations that have applied for participation in MDSAP and who have been granted a status of ''authorized'' or ''recognized'' by the MDSAP consortium after a prescribed assessment process conducted by the participating regulatory authorities. Participation in MDSAP is voluntary for device manufacturers regulated by FDA.

FDA utilizes the audit reports that are generated from MDSAP audits, rather than the certificate, as an additional tool for regulatory oversight of audited manufacturers. FDA conducts oversight activities of auditing organizations participating in MDSAP to ensure conformity to MDSAP and IMDRF policies and procedures. While both MDSAP and ISO 13485 audits cover the QMS requirements detailed in the standard, FDA cannot ensure that other FDA medical device requirements, such as parts 803, 806, 821, 830, are audited during independent ISO 13485 audits. Additionally, FDA does not conduct oversight of non-MDSAP auditing organizations and does not evaluate the content of audit reports issued outside of the MDSAP.

As such, FDA does not intend to require medical device manufacturers to obtain ISO 13485 certification and will not rely on ISO 13485 certificates to conduct its regulatory oversight of medical device manufacturers. For example, an ISO 13485 certificate will not be considered or accepted as a substitute for any oversight processes, including the performance of an inspection under section 704 of the FD&C Act or generation of an EIR. FDA inspections will not result in the issuance of a certificate of conformity to ISO 13485.

(Comment 80) Multiple comments recommended that FDA accept ISO 13485 certification in place of, or in combination with, FDA inspections. Some comments suggested that FDA clarify how a firm can achieve compliance with ISO 13485 if FDA does not accept certification to ISO 13485. A group of comments expressed a concern that entities that do not have certification will be unduly burdened by having to comply with the requirement to obtain certification where that is required by the regulatory authority, and also to comply with the requirements of the FD&C Act. Other comments recommended that FDA should allow entities that have obtained certification to utilize that certification to demonstrate compliance with the QMSR, in furtherance of global harmonization.

(Response) FDA disagrees with the comments that recommend the Agency accept certification to ISO 13485 in place of FDA inspections. In addition to the response to Comment 79 above, FDA also notes that ISO 13485 certificates are issued by organizations outside FDA. FDA's obligation remains to inspect medical device manufacturers to confirm compliance with the requirements of the FD&C Act and its implementing regulations, including not only the QMSR, but also other FDA medical device requirements, such as parts 803, 806, 821, and 830. Thus, FDA disagrees with the comments that it would be appropriate to accept certification to ISO 13485 in lieu of FDA inspection.

FDA also does not agree that it is unduly burdensome to comply with both certification to ISO 13485 (where that is required) and the QMSR. By way of this rulemaking, FDA is incorporating the requirements of ISO 13485 within the QMSR, which should simplify manufacturers' ability to comply with both ISO 13485 and requirements in the FD&C Act and its implementing regulations. Regardless of ISO 13485 certification, manufacturers must also comply with any additional and applicable requirements set forth in the FD&C Act.

(Comment 81) FDA received comments suggesting that because FDA's intent is to replace the QSIT approach with a new approach that follows the QMSR, FDA should outline and define the inspection procedures it intends to follow after the effective date of this rulemaking. Some commenters suggested that clarifying those procedures would provide manufacturers with more information on how to comply with the QMSR. Other comments recommended that FDA utilize the IMDRF to create the new inspection model, and that FDA utilize MDSAP techniques and consider multiple risk-based factors (including MDSAP enrollment and status, and ISO certification status) in developing its own inspection model.

(Response) Although this rule does not impact FDA's authority to conduct inspections under section 704 of the FD&C Act, FDA intends to replace its current inspection approach for medical devices, QSIT, with an inspection approach that will be consistent with the requirements of the QMSR. FDA understands that stakeholders are interested in knowing more details about FDA's inspection approach after this rule becomes effective and will determine in the future what details of our inspection model are appropriate to share. FDA notes that similar to the current QSIT inspection approach, these inspections will involve the collection of information to support observations

noted during the inspection and those included on a Form FDA 483, as appropriate and necessary. FDA inspections will not result in the issuance of certificates of conformance to ISO 13485 nor is FDA developing a certification program for ISO 13485. In addition, manufacturers with a certificate of conformance to ISO 13485 are not exempt from FDA inspections. FDA intends to engage in a variety of implementation activities, including, among other activities, updating information technology systems, training of personnel, finalizing the inspection approach, and assessing relevant regulations and other documents impacted by this rulemaking. FDA does not consider rulemaking to be the appropriate vehicle to describe any future implementation activities, including inspectional processes.

(Comment 82) Some comments recommended that FDA provide training and educational resources, and requested that FDA share its plan for updating appropriate guidance documents before the final rule becomes effective.

(Response) During this time, FDA intends to train FDA staff responsible for assessing compliance with medical device quality management system requirements, develop an inspection process, and assess relevant regulations and other documents impacted by this rulemaking, as appropriate. At this time, FDA considers the suggestion that it share a plan to be beyond the scope of this rulemaking.

(Comment 83) One comment recommended that after this rulemaking, FDA utilize the MDSAP inspection model in lieu of QSIT, for device-led combination products.

(Response) FDA disagrees with the recommendation, as combination products are currently outside the scope of the MDSAP program for FDA.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is a significant regulatory action under Executive Order 12866 section 3(f)(1).

Because this rule is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule falls within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Our small entities analysis (see Part III of the Final Regulatory Impact Analysis (Ref. 15)) indicates that the final rule would result in a net cost savings of over $500 million for medical device establishments deemed as small entities by the Small Business Administration. Therefore, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

We estimate that the QMSR will result in an annualized net cost savings (benefits) of approximately $507 million at a 7 percent discount rate and approximately $528 million in cost savings at a 3 percent discount rate. In addition to the cost savings to the medical device industry, the qualitative benefits of the rule include quicker access to newly developed medical devices for patients leading to improved quality of life of the consumers. The rule will also align part 820 with other related programs potentially contributing to additional cost savings.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 15) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the one-time and annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Medical Devices; Quality Management System; OMB control number 0910–0073—Revision

Description: FDA is revising its device CGMP requirements as set forth in the QS regulation, codified in part 820. Through this rulemaking, FDA is converging its requirements with QMS requirements used by other regulatory authorities from other jurisdictions (*i.e.,* other countries). We are doing so by incorporating by reference the current 2016 version of ISO 13485 and the current 2015 version of Clause 3 of ISO 9000.

Through this rulemaking we also establish additional requirements that help connect and align ISO 13485 with existing requirements in the FD&C Act and its implementing regulations and make conforming edits to the portion of the CFR governing combination products (part 4) to clarify the device CGMP requirements for such products.

Description of Respondents: Respondents to this information

collection are any manufacturers engaged in the design, manufacture, packaging, labeling, storage, installation, or servicing of a finished device, including, but not limited to, organizations that perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, as well as initial distributors of foreign entities that perform these functions.

While the provisions of this part do not apply to manufacturers of components or parts of finished devices, such manufacturers are encouraged to consider provisions of this regulation as appropriate.

Respondents are also manufacturers of human cells, tissues, and cellular and tissue-based products, as defined in 21 CFR 1271.3(d), that are devices.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Total capital costs
Learn the rule	25,294	1	25,294	2.22	56,153	$9,858,780
Burden for those respondents whose processes do not already comply with ISO 13485	5,352	1	5,352	64	342,528	49,871,733
Total					398,681	59,730,513

[1] There are no operating and maintenance costs associated with this collection of information.

The number of establishments currently registered with FDA is 28,303. However, we excluded from the estimated one-time burden establishments registered as ''initial importers'' because we believe that compliance effort by initial importers would remain the same before and after the implementation of the final rule (see Ref. 15). Therefore, we assume 25,294 establishments will undergo a one-time burden to learn the rulemaking. We model the one-time learning cost as the time required by medical device establishments' regulatory affairs expert to access and read the rule, approximately 2.22 hours. The average total access and learning cost for all affected entities is $9,858,780 (see Ref. 15).

In addition to learning the rule requirements, medical device establishments that are not in compliance with ISO 13485 when the rulemaking is implemented would incur one-time initial costs related to training of a regulatory compliance expert, updating information technology, and updating documents related to policy and procedures. The additional estimated cost burden for medical device establishments that are not in compliance with ISO 13485 when the rulemaking is implemented is $49,871,733 (see Ref. 15).

The estimated hour burden of these additional one-time activities is included under ''Burden for those respondents whose processes do not already comply with ISO 13485'' in table 1. In the Regulatory Impact Analysis for this rulemaking, we estimate there are 5,352 respondents that do not currently comply with ISO 13485 and that the average burden per recordkeeping is approximately 64 hours (Ref. 15). Because we do not have robust data on the number of firms that currently comply with ISO 13485, we are using very small domestic medical device manufacturing establishments to represent those who will proportionately bear a greater burden of one-time costs by the final rule. As such, for this analysis, and as discussed in the Regulatory Impact Analysis, we assume that very small medical device manufacturing establishments currently do not sell their products abroad and do not comply with ISO 13485 (Ref. 15).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Quality Management System (§ 820.10 and ISO 13485)	28,303	1	28,303	348	9,849,444
Control of records (§ 820.35)	28,303	1	28,303	2	56,606
Total					9,906,050

[1] There are no capital costs or operating and maintenance costs associated with this annual collection of information.
[2] Numbers have been rounded.

The current burden associated with recordkeeping requirements in part 820 is 10,239,552 hours annually (as approved by OMB January 23, 2023). Assuming a commensurate level of burden for cumulative recordkeeping activities, we reduce our estimate to 9,906,050 to reflect a reduction of 333,502 hours annually. We believe this reduction will result from aligning our regulatory framework with that used by other regulatory authorities to promote consistency in the regulation of devices.

Quality management system (§ 820.10 and ISO 13485). Under § 820.10, an organization subject to part 820 must document a QMS that complies with the applicable requirements of ISO 13485, as incorporated by reference in § 820.7, and other applicable requirements of part 820.

Under § 820.10(c), manufacturers of class II, class III, and certain class I devices, as listed in § 820.10(c), must

comply with the requirements in Design and Development, Clause 7.3, and its subclauses in ISO 13485. This amendment does not substantively change the current recordkeeping requirement.

Under § 820.10(d), manufacturers of devices that support or sustain life, the failure of which to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury, must comply with the requirements in Traceability for Implantable Devices, Clause 7.5.9.2 in ISO 13485, in addition to all other applicable requirements in this part. This amendment does not substantively change the current recordkeeping requirement.

Control of records (§ 820.35). Estimated burden for the recordkeeping requirements in § 820.35 is under ''Control of records (§ 820.35)'' in table 2. In addition to the requirements of Clause 4.2.5 in ISO 13485, Control of Records, the manufacturer must maintain certain records as provided for in § 820.35.

In addition to Clause 8.2.2 in ISO 13485, Complaint Handling, the manufacturer must maintain records of the review, evaluation, investigation, for any complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications. If an investigation has already been performed for a similar complaint, another investigation is not necessary, and the manufacturer shall maintain records documenting justification for not performing such investigation. For complaints that must be reported to FDA under part 803, complaints that a manufacturer determines must be investigated, and complaints that the manufacturer investigated regardless of those requirements the manufacturer must record the information listed in § 820.35(a). The reporting requirements of part 803 are approved under OMB control number 0910–0437 (title: Medical Device Reporting).

In adhering to Clause 7.5.4 in ISO 13485, Servicing Activities, the manufacturer must record the information listed in § 820.35(b), at a minimum, for servicing activities.

Under § 820.35(c), in addition to the requirements of Clauses 7.5.1, 7.5.8, and 7.5.9 of ISO 13485, the UDI must be recorded for each medical device or batch of medical devices.

Because the records required by § 820.35 should be readily available to the respondents, we estimate the average burden per response for § 820.35 to be no more than 2 hours. This estimate is in addition to the requirements of the applicable ISO 13485 Clauses, the burden for which is included under ''Quality Management System (§ 820.10 and ISO 13485)'' in table 2.

Device labeling and packaging controls (§ 820.45). In addition to the requirements of Clause 7.5.1 of ISO 13485, Control of production and service provision, manufacturers must document and maintain procedures that provide a detailed description of the activities to ensure the integrity, inspection, storage, and operations for labeling and packaging during the customary conditions of processing, storage, handling, distribution, and as appropriate, use of the device, including requirements to ensure labeling and packaging have been examined for accuracy prior to release or storage (§ 820.45(a)), the release of the labeling for use must be documented in accordance with Clause 4.2.5 of ISO 13485 (§ 820.45(b)), and results of the labeling inspection in § 820.45(c) must be documented in accordance with Clause 4.2.5 of ISO 13485. The estimated recordkeeping burden for ISO 13485, Clause 4.2.5, is part of the estimate for ''Quality Management System (§ 820.10 and ISO 13485)'' in table 2. There is no additional hour burden associated with § 820.45.

We received several comments related to the proposed rule. Descriptions of the comments and our responses are provided in section V. of this document, Comments on the Proposed Rule and FDA Response. We have not made changes to the estimated burden as a result of the comments.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. ISO 13485:2016, ''Medical devices—Quality management systems—Requirements for regulatory purposes,'' 3rd Ed., March 1, 2016.
* 2. FDA, ''Regulations Establishing Good Manufacturing Practices for the Manufacture, Packing, Storage, and Installation of Medical Devices.'' **Federal Register**, 43: 31508–31532, July 21, 1978.
3. ISO 13485:1996, ''Quality systems—Medical devices—Particular Requirements for the Application of ISO 9001,'' December 1996 (withdrawn). (Referenced at: *https://www.iso.org/standard/22098.html.*)
4. ISO 9001:1994, ''Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing,'' June 1994 (withdrawn).

(Referenced at: *https://www.iso.org/standard/16534.html*.)
* 5. FDA, ''Medical Device Single Audit Program (MDSAP).'' (Available at: *https://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap#:~:text=The%20Medical%20Device%20Single%20Audit,authorities%20participating%20in%20the%20program*.)
6. Global Harmonization Task Force. Guidance document, ''Implementation of Risk Management Principles and Activities Within a Quality Management System,'' May 20, 2005. (Available at: *https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n15r8-risk-management-principles-qms-050520.pdf*.)
7. ISO 14971, ''Medical Devices—Application of Risk Management to Medical Devices.'' (Available at: *https://www.iso.org/standard/72704.html*.)
* 8. ''Guidance for Industry, Third Parties and Food and Drug Administration Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program,'' (77 FR 16036, March 19, 2012). (Available at: *https://www.federalregister.gov/citation/77-FR-16036*.)
9. International Medical Device Regulators Forum, *http://www.imdrf.org/*.
*10. Device Good Manufacturing Practice Advisory Committee Panel meeting on March 2, 2022, Panel Transcript: *https://www.fda.gov/advisory-committees/advisory-committee-calendar/march-2-2022-device-good-manufacturing-practice-advisory-committee-meeting-announcement-03022022*.
11. International Standard, ISO 9000 ''Quality Management Systems—Fundamentals and Vocabulary,'' ISO 9000:2015; 4th Ed., September 15, 2015. (Available at: ISO 9000:2015(en), Quality management systems—Fundamentals and vocabulary.)
* 12. FDA, The Least Burdensome Provisions: Concept and Principles: Guidance for Industry and Food and Drug Administration Staff, February 5, 2019. (Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles*.)
* 13. FDA, Medical Device Accessories—Describing Accessories and Classification Pathways: Guidance for Industry and Food and Drug Administration Staff, December 20, 2017. (Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-accessories-describing-accessories-and-classification-pathways*.)
* 14. FDA, Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products, January 2017. (Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-requirements-combination-products*.)
* 15. FDA, ''Final Regulatory Impact Analysis, Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis; Medical Devices; Quality System Regulation Amendments.'' (Available at: *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.)

List of Subjects

21 CFR Part 4

Biologics, Drugs, Human cells and tissue-based products, Incorporation by reference, Medical devices.

21 CFR Part 820

Incorporation by reference, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 4 and 820 are amended as follows:

PART 4—REGULATION OF COMBINATION PRODUCTS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 360l, 360hh–360ss, 360aaa–360bbb, 371(a), 372–374, 379e, 381, 383, 394; 42 U.S.C. 216, 262, 263a, 264, 271.

■ 2. In § 4.2,

■ a. Revise the definition of ''Device''; and

■ b. Remove the definition of ''QS regulation'' and add in its place a definition for ''QMSR''.

The revision and addition read as follows:

§ 4.2 How does FDA define key terms and phrases in this subpart?

* * * * *

Device has the meaning set forth in § 3.2(f) of this chapter. A device that is a constituent part of a combination product is considered a finished device within the meaning of the Quality Management System Regulation (QMSR).

* * * * *

QMSR refers to the requirements under part 820 of this chapter.

* * * * *

■ 3. In § 4.4, revise paragraph (b)(1) and paragraph (b)(2) introductory text and add paragraph (f) to read as follows:

§ 4.4 How can I comply with these current good manufacturing practice requirements for a co-packaged or single-entity combination product?

* * * * *

(b) * * *

(1) If the combination product includes a device constituent part and a drug constituent part, and the current good manufacturing practice operating system has been shown to comply with the drug CGMP requirements, the following clauses of ISO 13485 (together with the definitions in Clause 3 of ISO 9000), which is incorporated by reference into the QMSR under § 820.7 of this chapter, and certain other provisions within the QMSR must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the QMSR need be made:

(i) *General requirements and management responsibility.* Clause 4.1, Clause 5 and its subclauses, Clause 6.1 of ISO 13485, and § 820.10 of this chapter;

(ii) *Design and development.* Clause 7.3 and its subclauses of ISO 13485. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained;

(iii) *Purchasing.* Clause 7.4. and its subclauses of ISO 13485;

(iv) *Analysis of data, improvement, and complaint handling.* Clause 8.2.2 and § 820.35(a) of this chapter, Clause 8.4, and Clause 8.5. and its subclauses of ISO 13485;

(v) *Installation activities.* Clause 7.5.3 of ISO 13485; and

(vi) *Servicing activities.* Clause 7.5.4 of ISO 13485 and § 820.35(b) of this chapter.

(2) If the combination product includes a device constituent part and a drug constituent part, and the current good manufacturing practice operating system has been shown to comply with the QMSR requirements for devices, the following provisions of the drug CGMP requirements must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the drug CGMP requirements need be made:

* * * * *

(f) The material listed in this paragraph (f) is incorporated by reference into this section 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 Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA at Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240–402–7500; *https://www.regulations.gov/document/FDA-*

2013-S-0610-0003. 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*. In addition, the terms and definitions given in ISO 9000:2015 are available for viewing, without cost, at *https://www.iso.org/obp/ui#iso:std:iso:9000:ed-4:v1:en.* This material is available from the International Organization for Standardization (ISO), BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; +41–22–749–01–11; *customerservice@iso.org, https://www.iso.org/store.html.*

(1) ISO 9000:2015(E), (''ISO 9000''), *Quality Management systems—Fundamentals and vocabulary,* Clause 3—*Terms and definitions,* Fourth edition, September 15, 2015.

(2) ISO 13485:2016(E), (''ISO 13485''), *Medical devices—Quality management systems—Requirements for regulatory purposes,* Third edition, March 1, 2016.

■ 4. Revise part 820 to read as follows:

PART 820—QUALITY MANAGEMENT SYSTEM REGULATION

Subpart A—General Provisions

Subpart B—Supplemental Provisions

Subparts C–O [Reserved]

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

Subpart A—General Provisions

§ 820.1 Scope.

(a) *Applicability.* Current good manufacturing practice (CGMP) requirements are set forth in this quality management system regulation (QMSR). The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to assure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act and that the use of other terminology, such as ''safety and performance,'' in this part does not change this statutory standard or the requirements of this part. Any manufacturers engaged in the design, manufacture, packaging, labeling, storage, installation, or servicing of a finished device must establish and maintain a quality management system that is appropriate for its specific device(s). Manufacturers subject to this part include, but are not limited to, manufacturers that perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, as well as initial distributors of foreign entities that perform these functions. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged.

(1) *Finished devices.* The provisions of this part shall apply to any finished device, as defined in this part, intended for human use, that is manufactured in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico, or that is imported or offered for import into the United States.

(2) *Components or parts.* The provisions of this part do not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to consider provisions of this regulation as appropriate.

(3) *Blood and blood components.* The provisions of this part do not apply to manufacturers of blood and blood components used for transfusion or for further manufacturing. Such manufacturers are subject to subchapter F of this chapter.

(4) *HCT/Ps.* The provisions of this part apply to manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this chapter, that are devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the Federal Food, Drug, and Cosmetic Act or under a biological product license application under section 351 of the Public Health Service Act). HCT/Ps regulated as devices are also subject to the donor-eligibility requirements set forth in part 1271, subpart C of this chapter and applicable current good tissue practice requirements in part 1271, subpart D of this chapter. In the event of a conflict between applicable regulations in part 1271 and in other parts of this chapter, the regulation specifically applicable to the device in question shall supersede the more general regulation.

(b) *Conflicts with other requirements under the Federal Food, Drug, and Cosmetic Act.* The QMSR for devices in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. To the extent that any applicable requirements in this part conflict with requirements in other parts of this chapter, the requirements specifically applicable to the device in question shall supersede the more generally applicable requirements. Moreover, to the extent that any clauses of ISO 13485 (incorporated by reference, see § 820.7) conflict with any provisions of the Federal Food, Drug, and Cosmetic Act and/or its other implementing regulations, the Federal Food, Drug, and Cosmetic Act and/or its other implementing regulations will control.

(c) *Foreign manufacturers.* A device that is imported or offered for import into the United States is subject to refusal of admission to the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act if, among other things, it appears to be adulterated as set forth in the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

(d) *Exemptions or variances.* (1) A manufacturer subject to any requirement under section 520(f)(1) of the Federal Food, Drug, and Cosmetic Act, including any requirements under this part, may petition for an exemption or variance from such requirement in accordance with section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act. Petitions for an exemption or variance shall be submitted in accordance with the procedures set forth in § 10.30 of this chapter.

(2) FDA may initiate and grant a variance from any requirement(s) in this part when the Agency determines that such variance is in the best interest of the public health, including that there is a public health need for the device and the device would not likely be made sufficiently available without the variance. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

§ 820.3 Definitions.

The definitions in ISO 13485 and in Clause 3 of ISO 9000 (incorporated by reference, see § 820.7) apply to this part, except as specified in paragraph (b) of this section, and do not affect the meaning of similar terms defined in this title.

(a) The following terms, which are either not used or not defined in ISO 13485 or in Clause 3 of ISO 9000, also apply for the purposes of this part:

Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly that is intended to be included as part of the finished, packaged, and labeled device.

Federal Food, Drug, and Cosmetic Act means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.,* as amended.

Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) of this chapter and that is also regulated as a device.

Remanufacturer means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

(b) All definitions in section 201 of the Federal Food, Drug, and Cosmetic Act shall apply to the regulation of quality management systems under this part and shall supersede the correlating terms and definitions in ISO 13485 (*e.g.,* the definitions of device and labeling in section 201(h) and (m) of the Federal Food, Drug, and Cosmetic Act apply to this part and supersede the definitions for the correlating terms in ISO 13485 (labelling and medical device)). In addition, the following terms and definitions apply to this part and supersede the definitions for the correlating terms in ISO 13485 or ISO 9000:

Implantable medical device shall have the meaning of ''implant'' as defined in section 860.3 of this chapter.

Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

Organization shall have the meaning of ''manufacturer'' as defined in this part.

Rework means action taken on a nonconforming product so that it will fulfill the specified requirements in the medical device file (MDF) before it is released for distribution.

Safety and Performance shall have the meaning of ''safety and effectiveness'' in Clause 0.1 of ISO 13485. The phrase ''safety and performance'' does not relieve a manufacturer from any obligation to implement controls or other measures that provide reasonable assurance of safety and effectiveness.

§ 820.5 [Reserved]

§ 820.7 Incorporation by reference.

Certain material is incorporated by reference into this part 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 Food and Drug Administration, and at the National Archives and Records Administration (NARA). Contact FDA at: Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240–402–7500; *https://www.regulations.gov/document/FDA-2013-S-0610-0003.* 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.* This material may be obtained from the International Organization for Standardization (ISO), BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; +41–22–749–01–11; *customerservice@iso.org, https://www.iso.org/store.html.*

(a) ISO 9000:2015(E) (''ISO 9000''), *Quality Management systems—Fundamentals and vocabulary,* Clause 3—*Terms and definitions,* Fourth edition, September 15, 2015. IBR approved for § 820.3.

(b) ISO 13485:2016(E) (''ISO 13485''), *Medical devices—Quality management systems—Requirements for regulatory purposes,* Third edition, March 1, 2016; IBR approved for §§ 820.1, 820.3, 820.10, 820.35, and 820.45.

§ 820.10 Requirements for a quality management system.

A manufacturer subject to this part as described by § 820.1(a) must:

(a) *Document.* Document a quality management system that complies with the applicable requirements of ISO 13485 (incorporated by reference, see § 820.7) and other applicable requirements of this part; and

(b) *Applicable regulatory requirements.* Comply, as appropriate, with the other applicable regulatory requirements in this title, including, but not limited to the following, to fully comply with the listed ISO 13485 Clause:

(1) For Clause 7.5.8 in ISO 13485, Identification, the manufacturer must document a system to assign unique device identification to the medical device in accordance with the requirements of part 830 of this chapter.

(2) For Clause 7.5.9.1 in ISO 13485, Traceability—General, the manufacturer must document procedures for traceability in accordance with the requirements of part 821 of this chapter, if applicable.

(3) For Clause 8.2.3 in ISO 13485, Reporting to regulatory authorities, the manufacturer must notify FDA of complaints that meet the reporting criteria of part 803 of this chapter.

(4) For Clauses 7.2.3, 8.2.3, and 8.3.3, advisory notices shall be handled in accordance with the requirements of part 806 of this chapter.

(c) *Design and development.* Manufacturers of class II, class III, and those class I devices listed in paragraph (c)(1) of this section and table 1 to paragraph (c)(2) of this section must comply with the requirements in Design and Development, Clause 7.3 and its Subclauses in ISO 13485. The class I devices are as follows:

(1) Devices automated with computer software; and

(2) The devices listed in the following table:

TABLE 1 TO PARAGRAPH (c)(2)

Section	Device
868.6810 ..	Catheter, Tracheobronchial Suction.
878.4460 ..	Glove, Non-powdered Surgeon's.
880.6760 ..	Restraint, Protective.
892.5650 ..	System, Applicator, Radionuclide, Manual.
892.5740 ..	Source, Radionuclide Teletherapy.

(d) *Devices that support or sustain life.* Manufacturers of devices that support or sustain life, the failure of which to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury, must comply with the requirements in Traceability for Implantable Devices, Clause 7.5.9.2 in ISO 13485, in addition to all other applicable requirements in this part, as appropriate.

(e) *Enforcement.* The failure to comply with any applicable requirement in this part renders a device adulterated under section 501(h) of the Federal Food, Drug, and Cosmetic Act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

Subpart B—Supplemental Provisions

§ 820.20—§ 820.30 [Reserved]

§ 820.35 Control of records.

In addition to the requirements of Clause 4.2.5 in ISO 13485 (incorporated by reference, see § 820.7), Control of Records, the manufacturer must include the following information in certain records:

(a) *Records of complaints.* In addition to Clause 8.2.2 in ISO 13485, Complaint Handling, the manufacturer shall maintain records of the review, evaluation, and investigation for any complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications. If an investigation has already been performed for a similar complaint, another investigation is not necessary, and the manufacturer shall maintain records documenting justification for not performing such investigation. For complaints that must be reported to FDA under part 803 of this chapter, complaints that a manufacturer determines must be investigated, and complaints that the manufacturer investigated regardless of those requirements, the manufacturer must record the following information:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s);

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) Any correction or corrective action taken; and

(7) Any reply to the complainant.

(b) *Records of servicing activities.* In adhering to Clause 7.5.4 in ISO 13485, Servicing Activities, the manufacturer must record the following information, at a minimum, for servicing activities:

(1) The name of the device serviced;

(2) Any UDI or UPC, and any other device identification(s);

(3) The date of service;

(4) The individual(s) who serviced the device;

(5) The service performed; and

(6) Any test and inspection data.

(c) *Unique Device Identification.* In addition to the requirements of Clauses 7.5.1, 7.5.8, and 7.5.9 in ISO 13485, the UDI must be recorded for each medical device or batch of medical devices.

(d) *Confidentiality.* Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.

§ 820.40 [Reserved]

§ 820.45 Device labeling and packaging controls.

In addition to the requirements of Clause 7.5.1 of ISO 13485 (incorporated by reference, see § 820.7), Control of production and service provision, each manufacturer must document and maintain procedures that provide a detailed description of the activities to ensure the integrity, inspection, storage, and operations for labeling and packaging, during the customary conditions of processing, storage, handling, distribution, and, as appropriate, use of the device.

(a) The manufacturer must ensure labeling and packaging has been examined for accuracy prior to release or storage where applicable, to include the following:

(1) The correct unique device identifier (UDI) or universal product code (UPC), or any other device identification(s);

(2) Expiration date;

(3) Storage instructions;

(4) Handling instructions; and

(5) Any additional processing instructions.

(b) The release of the labeling for use must be documented in accordance with Clause 4.2.5 of ISO 13485.

(c) The manufacturer must ensure labeling and packaging operations have been established and maintained to prevent mixups, including, but not limited to, inspection of the labeling and packaging before use to assure that all devices have correct labeling and packaging, as specified in the medical device file. Results of such labeling inspection must be documented in accordance with Clause 4.2.5 of ISO 13485.

Subparts C–O [Reserved]

Dated: January 22, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–01709 Filed 1–31–24; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL REGISTER

Vol. 89 Friday,

No. 23 February 2, 2024

Part IV

Department of Health and Human Services

42 CFR Part 8

Medications for the Treatment of Opioid Use Disorder; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 8

RIN 0930–AA39

Medications for the Treatment of Opioid Use Disorder

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (''HHS'' or ''the Department'').

ACTION: Final rule.

SUMMARY: This final rule modifies and updates certain provisions of regulations related to Opioid Treatment Program (OTP) accreditation, certification, and standards for the treatment of Opioid Use Disorder (OUD) with Medications for Opioid Use Disorder (MOUD) in OTPs. This includes making flexibilities put forth during the COVID–19 Public Health Emergency (PHE) permanent, as well as expanding access to care and evidence-based treatment for OUD. The final rule also removes all language and rules pertaining to the Drug Addiction and Treatment Act (DATA) Waiver from the regulations pursuant to the ''Consolidated Appropriations Act, 2023''.

DATES: The effective date of this final rule is April 2, 2024, and the compliance date is October 2, 2024.

FOR FURTHER INFORMATION CONTACT: Robert Baillieu, MD, MPH, Physician and Senior Advisor, SAMHSA/CSAT, 5600 Fishers Lane, Room 13–E–30, Rockville, MD, 20857, Phone: 202–923–0996, Email: *Robert.Baillieu@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: The discussion below includes an Executive Summary and overview describing the rule, responses to public comments, an impact statement, and other required regulatory analyses.

Executive Summary

A. Overview

This regulation finalizes the Department's proposed rule concerning Medications for the Treatment of Opioid Use Disorder published in the **Federal Register** on December 16, 2022 (87 FR 77330). It also finalizes proposals found in the Department's supplemental notice of proposed rulemaking concerning removal of the DATA–2000 Waiver requirements issued in the **Federal Register** on February 13, 2023 (88 FR 9221). The final rule makes changes to the Department's existing regulations concerning OTPs at 42 CFR part 8.

The Controlled Substances Act (CSA), under 21 U.S.C. 823(h)(1)-(3), provides that ''[t]he Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)'' if, among other things, the applicant ''is determined by the Secretary to be qualified (under standards established by the Secretary [of HHS]) to engage in the treatment with respect to which registration is sought[,]'' and ''if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.'' [1] The Secretary's standards authorized under section 823(h) have been published as regulations under part 8 of title 42 of the Code of Federal Regulations (''42 CFR part 8'' or ''part 8'').[2] Among other things, these regulations establish the procedures by which the Secretary of HHS determines whether a program is qualified to dispense opioid agonist medications in the treatment of opioid use disorders, and standards regarding the appropriate quantities of opioid agonist medications that may be provided for unsupervised use by individuals undergoing such treatment.[3] In addition, ''a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication'' that is also ''registered under 21 U.S.C. 823(h)(1)'' is described as an ''Opioid Treatment Program'' (OTP).[4]

On December 29, 2022, the 'Consolidated Appropriations Act, 2023' (Pub. L. No: 117–328) was enacted, resulting in the removal of requirements to obtain a waiver from the registration requirements of 21 U.S.C. 823(h)(1) for qualifying practitioners seeking to dispense or prescribe schedule III, IV, or V controlled substances that are FDA-approved for use in ''maintenance and detoxification treatment.'' Practitioners with a waiver under section 823(h)(2) were limited in the number of patients with OUD they may treat at any one time, and depending on the practitioner's experience or qualifications, this statutory limitation was set at either 30, 100, or 275.[5] The Secretary was also authorized to change the patient limitations by regulation, and qualifying practitioners had to satisfy the requirements of 42 CFR 8.610 through 8.655 ''(or successor regulations)'' in order to treat up to 275 patients, which was the maximum number under the law.[6]

In this final rule, the Department modifies certain provisions of part 8 to update OTP accreditation and certification standards, as well as treatment standards for the provision of medications for opioid use disorder (MOUD) as dispensed by OTPs. Pursuant to the 'Consolidated Appropriations Act, 2023' (Pub. L. No: 117–328), the final rule also removes language pertaining to requirements for individual practitioners to dispense (including by prescribing) certain types of MOUD with a waiver under 21 U.S.C. 823(h)(2). SAMHSA has developed this final rule in consultation with the Drug Enforcement Administration.

The final rule draws on experience from the COVID–19 Public Health Emergency (PHE), as well as more than 20 years of practice-based research. The COVID–19 PHE necessitated changes to policy guidance and legal exemptions to protect the public's health, promote physical distancing and to preserve patient and OTP staff safety. In March 2020, SAMHSA published guidance regarding flexibilities that could be leveraged in the provision of unsupervised doses of methadone and the use of telehealth when initiating buprenorphine.[7] These flexibilities represented the first substantial change to OTP treatment and medication delivery standards in more than 20 years, and their role in facilitating access to treatment is supported by research.

This final rule not only makes these COVID–19-related flexibilities permanent, but also updates standards

[1] *See* 21 U.S.C. 823(h)(1)–(3).

[2] For readability, the Department refers to specific sections of 42 CFR part 8 using a shortened citation with the ''§'' symbol except where necessary to distinguish title 42 citations from other CFR titles, such as title 45 CFR, and in footnotes where the full reference is used.

[3] *See* 42 CFR 8.1

[4] The terms ''narcotic drugs'' and ''detoxification treatment'' included in this paragraph are found in statute. SAMHSA recognizes that these terms can be stigmatizing for some people, and not aligned with current terminology. SAMHSA uses ''opioid agonist medications'' (see Treatment Improvement Protocol (TIP) 63) as an alternative to ''narcotic drugs'' and ''withdrawal management'' as the alternative to ''detoxification treatment''.

[5] Formally under 21 U.S.C. 823(h)(2)(B)(iii)

[6] Formally under 21 U.S.C. 823(h)(2)(B)(iii)(II)(dd). *See https://www.govinfo.gov/content/pkg/USCODE-2016-title21/html/USCODE-2016-title21-chap13-subchapI-partC-sec823.htm.*

[7] *See https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf* and *https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.*

to reflect an accreditation and treatment environment that has evolved since part 8 went into effect in 2001. Accordingly, the Department is updating part 8 to promote practitioner autonomy; remove discriminatory or outdated language; create a patient-centered perspective; and reduce barriers to receiving care. These elements have been identified in the literature and in feedback as being essential to promoting effective treatment in OTPs.[8] [9] [10]

To this end, the definition of a practitioner has been modified to refer to a provider who is appropriately licensed by the State to prescribe (including dispense) medications. Admission criteria have been updated, as required by section 1252(b) of the 'Consolidated Appropriations Act, 2023', to remove significant barriers to entry, such as the one-year requirement for opioid use disorder (OUD),[11] while also defining the scope and purpose of the 'initial' and 'periodic' medical examinations. The final rule also includes new definitions to expand access to evidence-based practices such as split dosing, telehealth and harm reduction activities. In addition, outdated terms such as 'detoxification' have been revised to remove stigmatizing language.

The Department promotes practitioner autonomy and individualized care by finalizing the provision containing the criteria for unsupervised doses of methadone. This includes removal from sole consideration the length of time an individual has been in treatment and requirements for rigid reliance on toxicology testing results that demonstrate complete and sustained abstinence from all substances prone to misuse. Based on the clinical judgment of the treating provider, patients may be eligible for unsupervised, take-home doses of methadone upon entry into treatment. This change recognizes the importance of the practitioner-patient relationship and is consistent with modern substance use disorder treatment standards.[12] It also allows for greater flexibility in creating plans of care that promote recovery activities such as employment or education, while also eliminating the barrier of frequent OTP visits for individuals without access to reliable transportation.[13]

Accreditation and certification standards have been updated to codify the use of online/electronic forms, and to reflect a modern treatment environment. Part 8 has also been updated to facilitate information sharing between Accreditation Bodies and SAMHSA, particularly in those circumstances where there have been changes or violations in accreditation. The final rule also clarifies administrative issues pertaining to accreditation, mobile medication units and interim treatment.

This final rule makes treatment in OTPs more accessible to patients, while also supporting evidence-based and patient-centered care. In creating these changes, SAMHSA has relied on published evidence, stakeholder feedback, public comments to the proposed rule and the need to expand access to care in the face of a growing overdose epidemic, exacerbated by the COVID–19 pandemic.[14] This is brought further into focus by the HHS declaration of a public health emergency for the opioid crisis which has been renewed regularly since 2017.[15] While the COVID–19 public health emergency expired as of May 11, 2023,[16] the lessons learned from the COVID–19 pandemic remain relevant for ensuring access to safe and effective substance use disorder treatment. The changes created by this final rule are expansive but are focused on permanently implementing the existing flexibilities and updating policies and practices that are based on evidence. In this way, SAMHSA believes that much of what is contained in the rule will not represent a significant burden for OTPs and, in fact, will reduce burdens and confer many benefits to providers and patients. The final rule, therefore, supports OTPs in their on-going provision of equitable and evidence-based care to often marginalized patients with OUD. The final rule also is consistent with the HHS Overdose Prevention Strategy and the National Drug Control Strategy, both of which call for increasing access to and the uptake of evidence-based treatments for substance use disorders.[17]

B. Background

As of June 2023, there are over 2,000 OTPs in the United States, providing care to over 650,000 patients.[18] These are the only settings within which methadone, a schedule II opioid receptor agonist, can be legally provided to patients with OUD outside the context of hospital admission or certain other special circumstances.[19]

An OTP is an accredited treatment program with SAMHSA certification and Drug Enforcement Administration (DEA) registration to administer and dispense opioid agonist medications that are approved by FDA to treat OUD. Such medications include methadone, buprenorphine, a schedule III partial opioid receptor agonist, and naltrexone which is an opioid receptor antagonist. For purposes of certification, OTPs must also offer adequate medical, counseling, vocational, educational, as well as other assessment and treatment services either onsite or by referral to an outside entity or practitioner.[20]

Practitioners treating OUD and the OTPs in which they practice must continuously adapt to evolving patterns of drug misuse. This is increasingly

[8] Suen LW, Coe WH, Wyatt JP, Adams ZM, Gandhi M, Batchelor HM, Castellanos S, Joshi N, Satterwhite S, Pérez-Rodríguez R, Rodríguez-Guerra E, Albizu-Garcia CE, Knight KR, Jordan A. Structural Adaptations to Methadone Maintenance Treatment and Take-Home Dosing for Opioid Use Disorder in the Era of COVID–19. Am J Public Health. 2022 Apr;112(S2):S112–S116. doi: 10.2105/AJPH.2021.306654. PMID: 35349324; PMCID: PMC8965183.

[9] Kleinman MB, Felton JW, Johnson A, Magidson JF. ''I have to be around people that are doing what I'm doing'': The importance of expanding the peer recovery coach role in treatment of opioid use disorder in the face of COVID–19 health disparities. J Subst Abuse Treat. 2021 Mar;122:108182. doi: 10.1016/j.jsat.2020.108182. Epub 2020 Oct 21. PMID: 33160763; PMCID: PMC7577312.

[10] Suen LW, Castellanos S, Joshi N, Satterwhite S, Knight KR. ''The idea is to help people achieve greater success and liberty'': A qualitative study of expanded methadone take-home access in opioid use disorder treatment. Subst Abus. 2022;43(1):1143–1150. doi: 10.1080/08897077.2022.2060438. PMID: 35499469.

[11] *See* 42 CFR 8.12(e)(1).

[12] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21–02–01–002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

[13] Ware OD, Frey JJ, Cloeren M, Mosby A, Imboden R, Bazell AT, Huffman M, Hochheimer M, Greenblatt AD, Sherman SA. Examining Employment and Employment Barriers Among a Sample of Patients in Medication-Assisted Treatment in the United States, Addictive Disorders & Their Treatment: December 2021—Volume 20—Issue 4—p 578–586 doi: 10.1097/ADT.0000000000000295.

[14] Tanz LJ, Dinwiddie AT, Snodgrass S, O'Donnell J, Mattson CL, Davis NL. A qualitative assessment of circumstances surrounding drug overdose deaths during the early stages of the COVID–19 pandemic. SUDORS Data Brief, No 2. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2022.

[15] *See https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[16] *See https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html*

[17] *See https://www.hhs.gov/overdose-prevention/. See also https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/21/fact-sheet-white-house-releases-2022-national-drug-control-strategy-that-outlines-comprehensive-path-forward-to-address-addiction-and-the-overdose-epidemic/*

[18] Data from the U.S. Department of Health and Human Services, Treatment Locator, at *https://findtreatment.gov/*

[19] See 21 CFR 1306.07.

[20] Substance Abuse and Mental Health Services Administration. (2015). Federal guidelines for opioid treatment programs. HHS Publication No. (SMA) PEP15–FEDGUIDEOTP. Rockville, MD: Substance Abuse and Mental Health Services Administration.

complicated by changes in controlled medication prescribing practices, supply chains and patterns of drug use. Indeed, the early opioid epidemic of the 1990s was characterized by an increased supply of prescription opioids.[21] By 2010, however, the U.S. began to see rapid increases in overdose deaths involving heroin [22] and then by 2013, synthetic opioids other than methadone—primarily illicitly manufactured fentanyl—contributed to a further rise in overdose-related deaths.[23] [24] The introduction of xylazine into the illicit drug supply and its associated harms further adds to an evolving, complex, and dangerous situation.[25]

The isolation, anxiety and reduced access to resources experienced by many during the COVID–19 pandemic has exacerbated substance misuse and overdose deaths. According to provisional data from the Centers for Disease Control and Prevention (CDC), a predicted 109,940 Americans died from a drug overdose in the 12-month period ending in January 2023.[26] Synthetic opioids (primarily illicitly manufactured fentanyl) appear to be the principal driver of overdose deaths, increasing 55 percent from 2019 to 2020 and further increasing 26 percent from 2020 to 2021.[27] Overdose deaths involving cocaine also increased by 22 percent from 2019 to 2020. These deaths are likely linked to co-use or mixing (by illicit producers) of cocaine with illicitly manufactured fentanyl or heroin.[28] The rise in fentanyl use or exposure, concurrent substance misuse, as well as overdose deaths, necessitates changes to part 8 that expand access to care, and promote engagement in OTP services, while also maintaining oversight and accreditation activities. Oversight and accreditation standards are supported as a means of promoting evidence-based care, while minimizing diversion and adverse patient and public health outcomes.

C. Regulatory Background

On January 17, 2001 (66 FR 4075), the Department issued final regulations for the use of opioid agonist medications (referred to as narcotic drugs at that time) in treatment and withdrawal management (referred to as detoxification at that time) of OUD. The final rule repealed the treatment regulations enforced by the Food and Drug Administration (FDA), and created a new regulatory system based on an accreditation model. In addition, the final rule shifted administrative responsibility and oversight from the FDA to SAMHSA. This rulemaking initiative followed a 1995 study, 'Federal Regulation of Methadone Treatment' [29] by the Institute of Medicine (IOM, now known as the National Academy of Medicine) and reflected recommendations by the IOM and several other entities to improve the treatment of OUD by allowing for increased medical judgment in the care of patients with OUD. The IOM report recommended that the FDA process-oriented regulations should be reduced in scope to allow more clinical judgment in treatment and greater reliance on guidelines. The IOM report also recommended designing a single inspection format, having multiple elements, that would (1) provide for consolidated, comprehensive inspections conducted by one agency (under a delegation of Federal authority, if necessary), which serves all agencies (Federal, State, local) and (2) improve the efficiency of the provision of methadone services by reducing the number of inspections and consolidating their purposes.

To address these recommendations, SAMHSA proposed a ''certification'' system based on accreditation. Under the system, an applicant organization who intended to dispense opioid agonist medications in the treatment of OUD must first obtain from SAMHSA, a certification that the applicant is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification depended upon the applicant organization obtaining accreditation from a private nonprofit entity, or from a State agency, that had been approved by SAMHSA to accredit OTPs.

Accreditation Bodies were directed to base accreditation decisions on a review of an application for accreditation and on surveys (onsite inspections) conducted every three years by OUD treatment experts. In addition, Accreditation Bodies must apply specific opioid treatment accreditation elements that reflect ''state-of-the-art'' opioid treatment guidelines. Further to this, accreditation standards required that OTPs have quality assurance systems that consider patient outcomes.

The 2001 final regulations replaced FDA 'approval' of programs, with direct government inspection in accordance with more detailed process-oriented regulations. These process-oriented regulations continue to prescribe many aspects of oversight and treatment. To this end, subpart B of the regulation addressed accreditation and includes steps that Accreditation Bodies must follow to achieve approval to accredit OTPs. It also set forth the Accreditation Bodies' responsibilities, including the use of accreditation elements during accreditation surveys. Subpart C described the sequence and requirements for obtaining certification and addressed how and when programs must apply for initial certification and renewal of their certification. Subpart D elucidated the procedures for review of the withdrawal of approval of the Accreditation Body or the suspension and proposed revocation of an OTP certification.

Since publication of the final rule in 2001, it has been updated on occasion to include new medications, such as buprenorphine, while also updating or adding new rules governing the provision of such medications. Subpart F, added in 2016, described criteria for increasing the patient limit for those practitioners meeting Federal requirements to prescribe buprenorphine to 275.[30]

On December 29, 2022, the 'Consolidated Appropriations Act, 2023' (Pub. L. No: 117–328), was signed into law and immediately eliminated the requirement for individual practitioners to obtain a waiver to prescribe certain schedule III—V medications for the treatment of OUD, commonly known as the ''DATA-Waiver.'' Before the Consolidated Appropriations Act, 2023 was enacted, ''qualifying practitioners'' were required to obtain waivers (formerly under 21 U.S.C. 823(h)(2))

[21] Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. MMWR MorbMortal Wkly Rep. 2011 Nov 4; 60(43):1487–1492.

[22] Rudd RA, Paulozzi LJ, Bauer MJ, Burleson RW, Carlson RE, Dao D, Davis JW, Dudek J, Eichler BA, Fernandes JC, Fondario A. Increases in heroin overdose deaths—28 states, 2010 to 2012.MMWR MorbMortal Wkly Rep. 2014 Oct 3; 63(39):849.

[23] Gladden RM, Martinez P, Seth P. Fentanyl law enforcement submissions and increases in synthetic opioid-involved overdose deaths—27 states, 2013–2014. MMWR MorbMortal Wkly Rep. 2016; 65:837–43.

[24] O'Donnell JK, Gladden RM, Seth P. Trends in deaths involving heroin and synthetic opioids excluding methadone, and law enforcement drug product reports, by census region—United States, 2006–2015. MMWR MorbMortal Wkly Rep. 2017; 66:897–903.

[25] *See https://www.samhsa.gov/sites/default/files/colleague-letter-xylazine.pdf.*

[26] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023.

[27] Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2023. Available at *http://wonder.cdc.gov.*

[28] Ibid.

[29] For full text, see: *https://www.ncbi.nlm.nih.gov/books/NBK232108/*

[30] See *https://www.federalregister.gov/documents/2016/07/08/2016-16120/medication-assisted-treatment-for-opioid-use-disorders.*

from the separate DEA registration requirement, under 21 U.S.C. 823(h), that is needed to enable dispensing of certain controlled medications used in maintenance or withdrawal management (''detoxification'') treatment of OUD. Section 1252(b) of the 'Consolidated Appropriations Act, 2023' (Pub. L. No: 117–328) also required removal of the one-year history of opioid misuse prior to admission to an OTP. This was included in the part 8 NPRM (87 FR 77330), and public comments supported the change.

In 2001 there were close to 900 OTPs, but that number has grown to over 2,000 by 2023.[31] Over this period, the incidence of fentanyl misuse has increased, escalating with the onset of the COVID–19 pandemic in early 2020. To protect the public's health and reduce the risk of COVID–19 infection among patients and providers, SAMHSA issued flexibilities in the provision of take-home doses of methadone and initiation of buprenorphine via telehealth, including through audio-only platforms, that allowed for continued treatment of OUD with reduced direct patient contact. Each of these flexibilities represented a significant change to previous treatment standards and are discussed in detail below. It is important to note that SAMHSA has issued extensions to both the initiation of buprenorphine via telehealth flexibility and methadone take-home flexibility, effective upon expiration of the COVID–19 Public Health Emergency, and in effect for the period of one year from the end of the COVID–19 Public Health Emergency, or until such time that the U.S. Department of Health and Human Services publishes final rules revising 42 C.F.R part 8, whichever occurs sooner.[32]

Flexibility For Methadone Medication Take-Home Doses in Opioid Treatment Programs

Among the existing standards for medication administration and dispensing of methadone are limitations on unsupervised or ''take-home'' use. These prior standards were established early in the history of methadone as a medication for OUD, and the criteria for determining whether a patient may be allowed take-home doses were restrictive, requiring daily visits to the OTP for extended periods of time, and adherence to strict measures of sustained stability as described in 42 CFR part 8.[33] These criteria can pose disruption to employment, education and other daily activities for patients, and several of the criteria reflect outdated biases that promote stigma and discourage people from engaging in care in OTPs.

In March 2020, as a result of the pandemic, SAMHSA issued exemptions that permitted State regulatory authorities to request blanket exceptions to allow patients to take-home more doses of methadone; 43 States and the District of Columbia did so.[34] With this flexibility, SAMHSA allowed OTPs to dispense up to 28 days of ''take-home'' methadone doses to ''stable'' patients for the treatment of OUD, and up to 14 doses of ''take-home'' methadone for ''less stable'' patients ''who the OTP believes can safely handle this level of take-home medication.'' [35] Although the duration of this flexibility was not initially specified, a SAMHSA FAQ published in April 2020, indicated that the flexibility was tied with the duration of ''the current national health emergency . . . .'' [36]

The intention of the methadone take-home flexibility was to reduce the risk of COVID–19 infection among patients and providers. Beyond this, the flexibility promotes individualized care that considers patient characteristics and program involvement beyond time in treatment. By reducing the burden on patients to visit the OTP daily, this flexibility may reduce stigma for those seeking treatment, while also providing more equitable access to care as telemedicine in OTPs is expanded. It also allows those who reside far from an OTP or who lack access to reliable transportation to receive treatment, while also being able to gain or maintain employment, attend school, care for loved ones and engage in other required activities of daily living.

The methadone take-home flexibility has been met with widespread support among patients,[37] OTPs,[38] and State authorities.[39] Patients reported that increased take-home doses of methadone left them feeling more respected as responsible individuals.[37] [40] In a national meeting, State authorities reported that the flexibilities were appreciated by patients and OTPs alike, with no significant change in rates of diversion seen since the COVID–19 PHE was declared.[41] Indeed, analysis of the relevant data indicates that the actual level of misuse, diversion or harm from methadone is more likely to occur when it is prescribed for pain as opposed to OUD, and that the rate of diversion is lower than that of oxycodone or hydrocodone.[42] Additionally, a survey found that diversion of methadone is low among patients receiving take-home doses under the COVID–19 PHE flexibility.[43] [44] Further to this, analysis of data on fatal overdoses from January 2019 to August 2021 demonstrated that this flexibility did not lead to more deaths involving methadone.[45]

[31] SAMHSA treatment locator. See *https://dpt2.samhsa.gov/treatment/directory.aspx.*

[32] *See https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance;* and *https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/buprenorphine-at-opioid-treatment-programs*

[33] *https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8?toc=1.*

[34] HHS Guidance for Opioid Treatment Programs. *https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf.*

[35] *See https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf.*

[36] See *https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.*

[37] Hatch-Maillette MA, Peavy KM, Tsui JI, Banta-Green CJ, Woolworth S, Grekin P. Re-thinking patient stability for methadone in opioid treatment programs during a global pandemic: Provider perspectives. J Subst Abuse Treat. 2021 May;124:108223. doi: 10.1016/j.jsat.2020.108223. Epub 2020 Dec 5. PMID: 33342667; PMCID: PMC8005420.

[38] Joseph G, Torres-Lockhart K, Stein MR, Mund PA, Nahvi S. Reimagining patient-centered care in opioid treatment programs: Lessons from the Bronx during COVID–19. J Subst Abuse Treat. 2021 Mar;122:108219. doi: 10.1016/j.jsat.2020.108219. Epub 2020 Dec 3. PMID: 33353790; PMCID: PMC7833302.

[39] ''To Save Lives From Opioid Overdose Deaths, Bring Methadone Into Mainstream Medicine'', Health Affairs Forefront, May 27, 2022.

[40] Krawczyk, N., Rivera, B. D., Levin, E., & Dooling, B. C. E. (2023). Synthesizing evidence of the effects of COVID–19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. The Lancet. Public health, 8(3), e238–e246. *https://doi.org/10.1016/S2468-2667(23)00023-3*

[41] The 2022 American Association for the Treatment of Opioid Dependence (AATOD) Conference, Baltimore, Maryland, October 30—November 3, 2022.

[42] NIDA. 2018, June. Medications to Treat Opioid Use Disorder. Retrieved from *https://irp.drugabuse.gov/wp-content/uploads/2019/12/NIDA-Medications-to-treat-opioid-use-disorder_2018.pdf.*

[43] Figgatt, MC, Salazar Z, Day E, Vincent L, Dasgupta N. Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID–19, Journal of Substance Abuse Treatment, Volume 123, 2021, *https://doi.org/10.1016/j.jsat.2021.108276.*

[44] Dooling, B.C.E. & Stanley, L.E. (2021). *Unsupervised use of opioid treatment medications: Report II of the extending pandemic flexibilities for opioid use disorder treatment project.* GW Regulatory Studies Center. *https://regulatorystudies.columbian.gwu.edu/unsupervised-use-opioid-treatment-medications.*

[45] Jones, C. M., Compton, W. M., Han, B., Baldwin, G., & Volkow, N. D. (2022). Methadone-

Continued

Recognizing the importance of this flexibility, SAMHSA released guidance on November 18, 2021, (subsequently updated on April 19, 2023) [46] that extended the methadone take-home flexibility for one year past the end of COVID–19 PHE (May 11, 2024), or until such time that the Department publishes this final rule, whichever occurs sooner.

The Opioid Treatment Program Flexibility To Prescribe MOUD via Telehealth Without an Initial In-Person Physical Evaluation

Telehealth is a mode of service delivery that has been used in clinical settings for over 60 years and empirically studied for just over 20 years.[47] [48] [49] Between 2016 and 2019, use of telehealth, in general, doubled from 14 to 28 percent [50] while substance use disorder (SUD) treatment, offered through telehealth over the same period, increased from 13.5 to 17.4 percent.[51] This trend has rapidly increased between 2019 and 2021, due to the COVID–19 pandemic.[52]

The pandemic spurred use of telehealth for the treatment of OUD with buprenorphine, a schedule III partial opioid receptor agonist. Prior to buprenorphine's development, the only opioid agonist that could be used to treat OUD was methadone dispensed through OTPs. Methadone has a relatively complicated pharmacological profile, necessitating closer observation of new patients to ensure that initial doses do not exceed an individual's tolerance for the medication.[53]

In response to the COVID–19 PHE, as declared by Secretary Azar on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), the DEA granted temporary exceptions to the *Ryan Haight Act* and DEA's implementing regulations under 21 U.S.C. 802(54)(D), one of the seven distinct categories of telemedicine envisioned under the statutory definition of the practice of telemedicine. In order to prevent lapses in care, these exceptions allowed for the prescribing of controlled medications via telemedicine encounters even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient.

These telemedicine flexibilities authorized practitioners to prescribe schedule II–V controlled medications via audio-video telemedicine encounters, including schedule III–V narcotic controlled medications approved by the Food and Drug Administration (FDA) for maintenance and withdrawal management treatment of opioid use disorder via audio-only telemedicine encounters, provided that such prescriptions otherwise comply with the requirements outlined in DEA guidance documents, DEA regulations, and applicable Federal and State law. DEA granted those temporary exceptions to the *Ryan Haight Act* and DEA's implementing regulations via two letters published in March 2020: the March 25, 2020 ''Dear Registrant'' letter signed by William T. McDermott, DEA's then-Assistant Administrator, Diversion Control Division,[54] and the March 31, 2020 ''Dear Registrant'' letter signed by Thomas W. Prevoznik, DEA's then-Deputy Assistant Administrator, Diversion Control Division.[55]

Building upon this, SAMHSA implemented OTP regulatory flexibilities designed to help address the impact of the COVID–19 pandemic on OTPs and their patients.[56] In April 2020, SAMHSA exempted OTPs from the requirement to perform an in-person physical evaluation (under 42 CFR 8.12(f)(2)) for any patient who was to be treated by the OTP with buprenorphine if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determined that an adequate evaluation of the patient could be accomplished via telehealth. The duration of this exemption was specifically tied with the ''period of the national emergency declared in response to the COVID–19 pandemic'',[57] and the exemption did not include induction of methadone via telehealth technology.

Recent research has demonstrated that telehealth can be an effective tool in integrating care and extending the reach of specialty providers,[58] and that among those patients requiring treatment with buprenorphine, there are high levels of satisfaction with the use of telehealth services.[59] Additionally, there are no significant differences between telehealth and in-person buprenorphine induction in the rate of continued substance use, retention in treatment or engagement in services.[58] [60] Research also shows that there is no significant difference in client and provider ratings of therapeutic alliance when using telehealth technology platforms.[59] Further to this, research demonstrates that actions to facilitate access to buprenorphine-based treatment for OUD during the COVID–19 pandemic were not associated with an increased proportion of overdose deaths involving buprenorphine.[61]

Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs. JAMA psychiatry, e221776. Advance online publication. *https://doi.org/10.1001/jamapsychiatry.2022.1776.*

[46] *See https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance*

[47] Bashshur, R. L., Shannon, G. W., Bashshur, N., & Yellowlees, P. M. (2016). The empirical evidence for telemedicine interventions in mental disorders. Telemedicine and e-Health, 22(2), 87–113.

[48] Lustig, T. (2012). The role of telehealth in an evolving health care environment: Workshop summary. National Academies Press.

[49] Mace, S., Boccanelli, A., & Dormond, M. (2018). The use of telehealth within behavioral health settings: Utilization, opportunities, and challenges. University of Michigan School of Public Health, Behavioral Health Workforce Research Center.

[50] American Medical Association (2019). Telehealth implementation playbook. Digital Health Implementation Playbook Series. *https://www.ama-assn.org/system/files/2020-04/ama-telehealth implementation-playbook.pdf*

[51] Uscher-Pines, L., Cantor, J., Huskamp, H. A., Mehrotra, A., Busch, A., & Barnett, M. (2020). Adoption of telemedicine services by substance abuse treatment facilities in the U.S. Journal of Substance Abuse Treatment, 117, 108060.

[52] Melamed OC, deRuiter WK, Buckley L, Selby P. Coronavirus Disease 2019 and the Impact on Substance Use Disorder Treatments. Psychiatr Clin North Am. 2022 Mar;45(1):95–107. doi: 10.1016/j.psc.2021.11.006. Epub 2021 Nov 12. PMID: 35219445; PMCID: PMC8585604.

[53] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21–02–01–002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

[54] William T. McDermott, DEA Dear Registrant letter, Drug Enforcement Administration (March 25, 2020), *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf.*

[55] Thomas W. Prevoznik, DEA Dear Registrant letter, Drug Enforcement Administration (March 31, 2020), *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf*

[56] OTPs are authorized to dispense narcotic maintenance and detoxification medication under 21 U.S.C. 823(h)(1) and regulated under 42 CFR part 8.

[57] *See https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.*

[58] Guille, C., Simpson, A. N., Douglas, E., Boyars, L., Cristaldi, K., McElligott, J., Johnson, D., & Brady, K. (2020). Treatment of opioid use disorder in pregnant women via telemedicine: A nonrandomized controlled trial. JAMA Network Open, 3(1), e1920177-e1920177.

[59] King, V. L., Brooner, R. K., Peirce, J. M., Kolodner, K., & Kidorf, M. S. (2014). A randomized trial of web-based videoconferencing for substance abuse counseling. Journal of Substance Abuse Treatment, 46(1), 36–42.

[60] Vakkalanka, J. P., Lund, B. C., Ward, M. M., Arndt, S., Field, R. W., Charlton, M., & Carnahan, R. M. (2022). Telehealth Utilization Is Associated with Lower Risk of Discontinuation of Buprenorphine: a Retrospective Cohort Study of US Veterans. Journal of general internal medicine, 37(7), 1610–1618. *https://doi.org/10.1007/s11606-021-06969-1.*

[61] Tanz, L. J., Jones, C. M., Davis, N. L., Compton, W. M., Baldwin, G. T., Han, B., & Volkow, N. D. (2023). Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID–19 Pandemic. JAMA

On May 9, 2023, SAMHSA issued guidance [62] that extended the buprenorphine telehealth flexibility for OTPs for one year past the end of COVID–19 PHE, or until such time that the Department publishes this final rule, whichever occurs sooner. In the face of an escalating overdose crisis and an increasing need to reach remote and underserved communities, making the buprenorphine telehealth flexibility permanent is of paramount importance. This final rule permits initiation of buprenorphine at the OTP, by the OTP practitioner, if an OTP physician, primary care physician, or other authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be, or was, accomplished via audio-only or audio-visual telehealth technology.

SAMHSA believes that evidence underlying the initiation of buprenorphine using telehealth also is applicable to the treatment of OUD with methadone, and warrants expanding access to methadone therapy by applying some of the buprenorphine in-person examination flexibilities to treatment with methadone in OTPs.[63] However, SAMHSA also acknowledges that there are differences between these two medications. Accordingly, this final rule allows for the use of audio-visual telehealth for any new patient who will be treated by the OTP with methadone if a program physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform. SAMHSA is not extending this change to the use of audio-only telehealth platforms in assessing new patients who will be treated by the OTP with methadone because methadone, in comparison to buprenorphine, holds a higher risk profile for sedation in patients presenting with mild somnolence which may be easier to identify through an audio-visual telehealth platform. The final rule is not applicable to, and does not authorize, the prescription of methadone pursuant to a telehealth visit. Instead, this change applies to the ordering of methadone by appropriately licensed OTP practitioners and dispensed to the individual patient by the OTP under existing OTP procedures.

Further to this, health care providers who receive Federal financial assistance are reminded of their obligations to ensure that their audio-only and audio-visual telehealth platforms are accessible to individuals with disabilities and afford an opportunity for meaningful access for limited English proficient (LEP) individuals. Federal civil rights laws prohibit discrimination on the basis of disability and may require health care providers to make reasonable modifications to their policies, practices, or procedures to ensure that a person who is not able to use audio-visual telehealth platforms based on their disability has an equal opportunity to benefit from treatment with MOUD. Similarly, Federal civil rights laws prohibit discrimination on the basis of national origin (including language ability) and require recipients to take reasonable steps to provide meaningful access to LEP individuals. This may require the provision of a qualified interpreter and/or translated material, such that they have the opportunity benefit from treatment with MOUD.

Expanding Access to Services

On June 28, 2021, the DEA introduced allowance for OTPs to add a ''mobile component'' to their existing registration and waived any obligation for an OTP mobile medication unit complying with these requirements to separately register at the remote locations where it dispenses.[64] On September 21, 2021, SAMHSA released guidance on the establishment of mobile and non-mobile medication units and allowable services.[65] While part 8 currently allows OTPs certified by SAMHSA to establish medication units (as defined under 42 CFR 8.2), the final rule further defines mobile units and clarifies potential services, interventions and accreditation processes.

Additionally, the COVID–19 pandemic highlighted the importance of providing harm reduction services to OTP patients. On April 7, 2021, the CDC and SAMHSA jointly announced that Federal funding could be used to purchase rapid fentanyl test strips (FTS) for drug checking purposes.[66] This was proposed in part to help curb the dramatic spike in drug overdose deaths largely driven by the use (both intentional and unintentional) of potent synthetic opioids, primarily illicitly manufactured fentanyl. FTS can be used to determine if drugs have been mixed or cut with fentanyl, providing people who use drugs and their communities with important information about fentanyl in the illicit drug supply so they can take steps to reduce their risk of overdose.

On December 16, 2022, HHS issued a notice of proposed rulemaking (NPRM) entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330). In that NPRM, the Department proposed to modify certain provisions of part 8 to update Opioid Treatment Program (OTP) accreditation and certification standards, treatment standards for the provision of medications for opioid use disorder as dispensed by OTPs, and requirements for individual practitioners eligible to dispense (including by prescribing) certain types of Medication for Opioid Use Disorder (MOUD) with a waiver under 21 U.S.C. 823(h)(2). Proposed changes sought to make flexibilities put forth during the COVID–19 PHE permanent, and to also update standards to reflect an OTP accreditation and treatment environment that has evolved since 42 CFR part 8 came into effect in 2001. To this end, the Department proposed to update part 8 by: removing outdated language; fostering a more patient-centered perspective; and reducing barriers to receiving care. These elements have been identified in the literature and in feedback as being essential to promoting effective treatment and retention in care provided by OTPs.

To expand access to care, the Department proposed to update OTP admission criteria as described in 42 CFR part 8. This included removal of the one-year requirement for opioid addiction before admission to an OTP, in favor of consideration of problematic patterns of opioid use. Indeed, evidence-based standards of care demonstrate that it is more prudent to admit those individuals who either: meet diagnostic criteria for active moderate to severe OUD; are in OUD remission; or are at high risk for recurrence or overdose. In conjunction with updated standards that include extended take-home doses of methadone and access to telehealth, this is likely to

network open, 6(1), e2251856. *https://doi.org/10.1001/jamanetworkopen.2022.51856*

[62] See: *https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/buprenorphine-at-opioid-treatment-programs*

[63] Chan B, Bougatsos C, Priest KC, McCarty D, Grusing S, Chou R. Opioid treatment programs, telemedicine and COVID–19: A scoping review. Subst Abus. 2022;43(1):539–546. doi: 10.1080/08897077.2021.1967836. Epub 2021 Sep 14. PMID: 34520702.

[64] *See https://www.federalregister.gov/documents/2021/06/28/2021-13519/registration-requirements-for-narcotic-treatment-programs-with-mobile-components.*

[65] *See https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines#mobile.*

[66] *See https://www.samhsa.gov/newsroom/press-announcements/202104070200*

expand access while also improving retention in treatment.

Additionally, the Department proposed to update 42 CFR part 8 to reflect evidence-based practice, treatment standards, and the workforce currently providing services in OTPs. Proposed changes included: expanding the definition of a treatment practitioner to include any provider who is appropriately licensed to dispense and/or prescribe approved medications; addition of evidence-based paradigms of care such as split dosing, telehealth and harm reduction activities; removing outdated terms such as 'detoxification'; review of criteria for provision of take-home doses of methadone; strengthening the patient-practitioner relationship through promotion of shared and evidence-based decision making; allowing for early access to take-home doses of methadone for all patients to promote flexibility in creation of plans of care that promote recovery activities such as employment or education, while also allowing those with unstable access to reliable transportation the opportunity to also receive treatment; promotion of mobile medication units to expand an OTP's geographic reach; and review accreditation standards. The proposed changes sought to organize existing flexibilities and practice updates in a manner that makes them permanent and cohesive.

Removal of DATA-Waiver Requirements

Section 1262(a)(1) of the Consolidated Appropriations Act, 2023 (Pub. L. No: 117–328), which was enacted on December 29, 2022, amended the CSA (21 U.S.C. 823(h)) by eliminating the requirement that practitioners obtain a waiver to prescribe certain schedule III—V medications for the treatment of opioid use disorder (OUD). This immediately removed the requirement for practitioners to submit a notification of intent and to receive the Drug Addiction Treatment Act of 2000 (DATA)-Waiver before prescribing buprenorphine.

Before the Consolidated Appropriations Act, 2023 was enacted, ''qualifying practitioners'' were required to obtain waivers (formerly under 21 U.S.C. 823(h)(2)) from a separate registration requirement, under 21 U.S.C. 823(h), that is needed to enable dispensing of certain schedule II—V narcotic medications used in maintenance or detoxification treatment. Practitioners with a waiver of this kind were limited in the number of patients they could treat with this type of medication at any one time.

In July 2016, SAMHSA published a final rule (81 FR 44711) that added 'subpart F' to 42 CFR part 8 under the authority of former 21 U.S.C. 823(h)(2)(B)(iii)(III). Among other things, subpart F authorized eligible practitioners with a waiver under 21 U.S.C. 823(h)(2) to request approval to treat up to 275 patients under certain conditions. The December 16, 2022, NPRM entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330), proposed three changes to subpart F: (1) altering section headings to remove the current question-and-answer style and replacing it with a standard format; (2) updating Section 8.610 to remove stigmatizing language and to also clarify that the 275-patient waiver is limited to three years in duration and; (3) removing Section 8.635 to eliminate annual reporting requirements for practitioners approved to treat up to 275 patients.

Pursuant to section 1262 of the Consolidated Appropriations Act, 2023, the Department published a supplemental notice of proposed rulemaking (SNPRM), entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA–2000 Waiver Requirements' (88 FR 9221), on February 13, 2023. This SNPRM proposed to remove in its entirety subpart F of 42 CFR part 8 in addition to language throughout 42 CFR part 8 that specifically references or implicates the DATA–2000 waiver process.

D. Analysis and Discussion of Comments

On December 16, 2022, the Department published a notice of proposed rulemaking entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330). The public comment period ended on February 14, 2023, and a total of 373 comments were received. On February 13, 2023, the Department also released a supplemental NPRM entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA–2000 Waiver Requirements' (88 FR 9221), to bring proposed changes to 42 CFR part 8 rule into alignment with the 'Consolidated Appropriations Act, 2023' (Pub. L. 116–260). The supplemental NPRM closed for public comments on March 14, 2023. An additional 27 comments were received, the majority of which pertained to the December 16, 2022, NPRM.

General Comments

Terminology Changes, and Reducing Stigma

Comments conveyed widespread approval of terminology and language changes aimed at expanding care while also reducing stigmatization for patients receiving treatment for OUD. Some commenters noted that language changes alone will not be sufficient to eliminate, stigma, injustice, and institutionalized marginalization. Others were concerned that updated language was not accurate—for example, that it detracts focus from other forms of treatment. One commenter additionally suggested that SAMHSA and other authorities consider updating their organizations' names to maintain consistency with destigmatizing language changes. Such changes have been proposed by SAMHSA and HHS,[67] but not yet enacted by Congress as of this date.

Another commenter suggested eliminating or reducing the requirements for random toxicology testing as an important method to further reduce stigma and loss of bodily autonomy among a population that has often faced violent and punitive treatment. They also suggest reexamining the differential regulation of methadone versus buprenorphine.

Response: SAMHSA recognizes the role of language in perpetuating stigma and discrimination, and is committed to taking steps to use language that is positive, patient-centered, productive and inclusive. It recognizes that changing language, alone, will not immediately eliminate harms suffered by those struggling with and in recovery from substance use disorders. SAMHSA and its Federal, State, local, Tribal and territorial partners have been working to impact health equities and promote justice through its programs, services and regulations, as evidenced in the improvements made in this regulatory language. SAMHSA has also emphasized support for recovery and recovery services.[68] It will take time to assure consistency of language throughout documents; changing names of Federal agencies requires legislative action. Toxicology testing is a clinical tool that is used to inform the treatment process, should never be used punitively, and must be conducted in a way that is respectful of the individual and in accordance with clinical and

[67] *See https://www.samhsa.gov/sites/default/files/samhsa-fy-2024-cj.pdf.*

[68] *See https://www.samhsa.gov/find-help/recovery*?

professional standards.[69] Also, the different regulation of methadone (in schedule II) versus buprenorphine (in schedule III) stems from how these substances are scheduled and from how they are regulated under 21 U.S.C. 823(h), which requires ''practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment'' to obtain an annual separate registration for that purpose.

Error in Citations

One commenter expressed concern that several cited research studies were not accurately interpreted as used for this NPRM. For example, citation 103 is used as justification for provision of counseling at OTPs, but the study was done in a primary care setting. Another commenter stated that the same reference, 103, is incorrect and the citation in the body does not match the DOI link—one references HIV testing in Africa while it appears they intend to reference the HSU study on psychiatric comorbidity.

Response: SAMHSA made every effort to ensure that the citations listed were correct. The error noted with citation 103 has been rectified. Within the body of the text, the citation is appropriate as the text explicitly describes this study and highlights that in combination with other evidence, a comprehensive approach to treatment is associated with improved outcomes. Indeed, the proposed rule also includes evidence from other settings such as Emergency Departments. It is important to note that economic analysis of OUD treatment interventions is uncommon and so assessment of such evidence requires consideration of all sources.

Comments on Accreditation Standards

One-Year Accreditation Following One Recommendation

Many commenters opposed the proposed change under Section 8.4, that provides, based on their understanding, only one-year accreditations to OTPs with recommendations. They believe this change in accreditation regulations will essentially end three-year accreditations. Commenters stated that with the number of standard ratable elements it is unreasonable to expect facilities to meet every accreditation element. With about 1,400 elements evaluated during each survey, not having even one recommendation is an unobtainable standard for many OTPs. Commenters stressed that having such a high standard would result in a substantial number, if not all, of OTPs having to submit to an annual accreditation inspection.

Response: Section 8.4 addresses the responsibilities of the Accreditation Bodies. Since 2001, Section 8.4(b), in response to noncompliant programs stated ''(1) If an Accreditation Body receives or discovers information that suggests that an OTP is not meeting Federal opioid use disorder treatment standards, or if survey of the OTP by the Accreditation Body otherwise demonstrates one or more deficiencies in the OTP, the Accreditation Body shall as appropriate either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies.'' The proposed rule retained language about noncompliance with one or more standards as it refined expectations for Accrediting Bodies' follow up with these programs. Based on comments, this final rule clarifies the intent of this subpart and survey and accreditation requirements, while also explicitly clarifying that non-critical findings would not result in only a one-year accreditation.

Implementation Schedule Not To Exceed 60 Days

One comment drew attention to the 33% reduction in time this proposed change allows for submitting an implementation schedule, pursuant to Section 8.4. The commenter believes this would introduce significant new barriers to the delivery of care to persons with OUD while doing nothing to improve the standard of care. Other commenters agreed that 60 days is an insufficient amount of time to adequately address recommendations in a manner that improves patient care.

Response: SAMHSA thanks commenters for this information. Based on the comments, the time frames allotted for noncompliant OTPs to implement corrections in section 8.4 were extended to 180 days. This recognizes that some corrective measures may take more than 60 days to successfully implement.

Surveyor Subjectivity and Need for Flexibility

In reference to Section 8.4, several commenters mentioned that accreditation surveys are affected by the subjective interpretations of individual auditors, and that this subjectivity contributes to their objection to one recommendation being a preclusion for a three-year accreditation. Some OTP guidelines may no longer be consistent with newly proposed rules and are inconsistent with current evidence-based practices. Further, several commenters urged flexibility in accreditation decisions as the unique situations of many OTPs prevents constant, exact compliance. In other words, commenters urged flexibility in decision making based on center needs and circumstances as well as the seriousness of the recommendation(s) and its effect on patient care and safety.

Response: SAMHSA reviews the policies and procedures of all Accreditation Bodies, including those related to the training and supervision of surveyors. SAMHSA meets regularly with the Accrediting Bodies to assure consistency in the application and interpretation of 42 CFR part 8. It also reviews the performance of Accreditation Bodies by inspecting a selected sample of the OTPs accredited by the respective Body each year, and, under section 8.4 will receive reports of OTP surveys when deficiencies are discovered. Together, these help to ensure consistency across and within Accreditation Bodies. Following finalization of this rule, SAMHSA intends to update the 2015 Federal Guidelines for OTPs [70] to assure the OTP guidelines are consistent with newly proposed rules and with current evidence-based practices.

Cost Burden

Commenters reported concern that proposed changes to accreditation, in Section 8.4, will result in more frequent inspections, which will require significant time and financial expenditures. Commenters expressed their conviction that the increased frequency of inspections will take providers away from patient care and direct the focus of both providers and administrators away from patient needs. Furthermore, inspections have financial costs for OTPs; some commenters asserted that the cost to some OTPs of more frequent surveys might be more than the OTP can financially bear. Many commenters fear that the additional administrative and financial costs will lead to fewer OTPs and thus reduced options for patients in dire need of treatment.

Response: SAMHSA has made changes to Section 8.4 of this final rule to respond to commenter concerns about potentially increased rates of one-year accreditation results. In the final rule, Section 8.4(b) has been altered to not only clarify the criteria for one-year or three-year accreditation, but to also

[69] *See https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf.*

[70] *See https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf.*

remove potential misunderstanding around whether a specific number of recommendations might lead to less than three-year accreditations. Rather than implement a specific number of recommendations that might lead to less than three-year accreditation, the final rule determines the length of accreditation based on the severity of the non-compliance. With this clarification in the final rule, rates of one year accreditation and repeat surveys are not expected to increase.

Comments on Treatment Standards

MOUD Treatment Criteria Changes

Commenters overwhelmingly conveyed support for discontinuing requirements for a one-year history of OUD to access treatment as well as support for those changes that update admission criteria for minors. Some commenters also suggested that SAMHSA should remove the requirement that individuals cannot initiate methadone treatment more than twice a year.

Response: The final rule removes the requirement, previously at 8.12(e)(2), that minors are required to have had two documented unsuccessful attempts at short-term ''detoxification'', or withdrawal management, or drug-free treatment within a 12-month period to be eligible for maintenance treatment, and that those seeking withdrawal management, previously under 8.12(e)(4), cannot initiate methadone treatment more than twice per year. Instead, OTPs shall ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: the person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. There is nothing stated within the Federal regulations or statutes that limits the number of times a person can initiate treatment with methadone or any other medication.

Interim Treatment

Comments supported extending interim treatment from 120 days to at least 180. Commenters request the availability of interim maintenance treatment through all OTPs and not just public and private not-for-profit OTPs, pursuant to 8.12(j)(1). Some commentors suggested interim treatment provision in primary care providers' offices.

Response: Interim treatment was developed to expand access to OTP services in urgent circumstances. The proposed rule specifically amended the duration of interim treatment from 120 days to 180 days so that on a temporary basis, a patient may receive services from an OTP, while awaiting access to more comprehensive treatment services. Language pertaining to public and not-for-profit OTPs has been removed from the final rule in order to expand access to interim treatment among all OTPs. This is done in recognition of a need to bring individuals into treatment and in response to public comment.

Expanding the Definition of Long-Term Care Facilities

There is widespread support among commenters for the addition of jails and prisons under the definition of long-term care facilities at 8.11(h)(3), thus expanding the waiver of OTP certification to better allow for equitable access to treatment and reduce the potential for civil rights violations. Group homes and withdrawal management programs are also mentioned by some commenters in this context, as well as any licensed non-hospital residential treatment programs with medical staffing, a DEA registration and the ability to administer/store/dispense prescription medications. Several commenters also requested the removal of waiver language that specifies the OUD diagnosis be secondary to another condition.

Response: Language has been added to the final rule, at Section 8.11(h)(3), to highlight that these flexibilities may apply to a correctional facility that has registered with the DEA as a hospital/clinic. If a correctional facility has registered as a hospital/clinic, a physician or authorized staff may administer or dispense narcotic drugs to maintain or manage withdrawal for an inmate as an incidental adjunct to medical or surgical treatment of conditions other than addiction. Rules regarding controlled substance dispensing that is outside the context of OTPs, such as waiver language that specifies the OUD diagnosis be secondary to another condition, is beyond the scope of this rulemaking. SAMHSA notes that the Centers for Medicare & Medicaid Services released new guidance encouraging States to apply for a new Medicaid re-entry Section 1115 waiver demonstration project for those persons leaving jails and prisons that this final rule may help facilitate.[71]

Expanding Methods of Access via OTPs and Their Mobile Units

Commenters support easing pathways, under section 8.11, for opening new OTPs by enacting changes to ease or eliminate barriers, such as extending certification periods, providing funding opportunities, or encouraging existing syringe service programs to grow into new OTPs. Commenters also support expanding geographical access at current OTPs by easing regulations on their mobile units. They remarked on transportation challenges for people with OUD and that having access to mobile units will assist those who otherwise might not be able to attend a clinic in a fixed location.

Response: Recognizing the many pathways to expanding access, the final rule makes permanent flexibilities implemented during the COVID–19 PHE and updates the overall regulations to reflect ways in which the accreditation and treatment environment has evolved since part 8 went into effect in 2001. Proposed changes that facilitate delivery of comprehensive services in mobile units, such as the use of telehealth, have been made permanent as they reduce barriers to receiving care, among other goals. Regulations regarding mobile units were eased by the DEA and SAMHSA, and use of funds allocated to States under the Block Grant were approved for use in the purchase of mobile units.[72] Some commenters reference State-specific regulations that limit mobile units, but Federal OTP regulations do not preempt separate State requirements. SAMHSA fully encourages and facilitates additional OTP applications.[73]

Expanding Methods of Access via Office and Community Settings

Many commenters emphasized that methadone treatment must be allowed outside of OTPs, such as in office-based settings or dispensing in community pharmacies, as many communities do not have access to OTPs. Commenters asserted that this approach has been successfully implemented in other countries and SAMHSA must work with the DEA to move in this direction. Furthermore, this may help to address stigma associated with and criticism of some OTPs and will help promote the cultural view of OUD as a chronic disease that necessitates respectful patient-centered care.

[71] *See https://www.cms.gov/newsroom/press-releases/hhs-releases-new-guidance-encourage-states-apply-new-medicaid-reentry-section-1115-demonstration.*

[72] *See https://www.samhsa.gov/sites/default/files/2021-letter-state-authorities-mobile.pdf.*

[73] *See https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program.*

Response: The final 42 CFR part 8 rule only applies to dispensing of methadone in OTPs. SAMHSA continues to work with Federal partners to explore ways through which access to MOUD might be expanded.

Expanding the Definition of a Practitioner

There was strong support from commenters regarding expanding the definition of providers, under Section 8.2, who are able to prescribe or order medications. Commenters expressed that allowing licensed practitioners, such as physician assistants, nurse practitioners, and certified nurse midwives, will result in improved access to patients, especially in areas with a high level of provider shortages. There was further support to add pharmacists to the definition of qualified providers. Commenters felt that including pharmacists as qualified providers will further improve accessibility for people suffering with OUD.

Response: Pursuant to the supplemental notice of proposed rulemaking entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA–2000 Waiver Requirements' (88 FR 9221) requirements for staff credentials are finalized to include the definition of a practitioner as ''a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP''. The scope of 42 CFR part 8 is also limited to activities within an OTP.

One commenter requested clarification on the context of certified nurse-midwives (CNMs) practice with MOUD. Another commenter requested clarification on scope of practice for physician assistants and nurse practitioners prescribing methadone, as there appear to be more restrictions compared to buprenorphine.

Response: As noted above, the definition of a practitioner was modified. However, not all States allow CNMs, nurse practitioners, physician assistants, or pharmacists to order methadone unless supervised by a physician. Notwithstanding additional flexibilities provided in this final rule, practitioners must continue to adhere to State requirements that may apply to the provision of methadone and scope of practice. As also noted, this final rule does not apply to the prescribing of methadone for OUD outside of OTPs.

Food and Drug Administration (FDA) Approval of Testing Supplies

Some commenters requested the removal of the proposed change requiring drug testing services be FDA approved, under Section 8.12(f)(6), as this would impede their ability to test for fentanyl with an instant testing method. Another commenter requested more clarity, stating that this rule could preclude what they view as medically necessary definitive testing at qualified laboratories, despite the lack of an FDA review pathway for such testing. As the drug supply continues to rapidly evolve, OTP medical directors need the flexibility to use the best available tests, regardless of FDA approval, to provide effective patient care.

Response: SAMHSA has amended Section 8.12(f)(6) to specifically allow for distribution of testing strips for drug checking, to those patients who wish to test their supply for adulteration, where not prohibited by law. The final rule also clarifies that FDA approved tests be used when conducting random drug testing with patients, including urine or saliva samples, at the OTP.

Support for Provision of Resources With Patient-Centered Care Plans

Commenters were supportive of Section 8.12(5)(i) that requires OTPs to work with patients to provide additional services such as counseling and harm reduction (including education, testing, and treatment for HIV, viral hepatitis, and sexually transmitted infections (STIs) when helpful), but some commenters cautioned requiring provision of these services without establishing their funding and requested in the meantime that the language be amended to include assessment and referral. Additionally, comments overwhelmingly conveyed support for clarifying that attending counseling is not a condition of MOUD treatment, and that treatment plans should be patient centered.

Response: Part 8 defines what is expected in the provision of methadone for the treatment of OUD. Although it is expected that OTPs plan for their fiscal viability to assure continuity of medication and other treatment services, funding and sustainability are beyond the scope of these regulations.

OTPs are expected to offer adequate medical, counseling, vocational, educational, and other assessment, and treatment services either onsite or by referral to an outside agency or practitioner. The revisions in this final rule promote a patient-centered approach to care that does not make medication continuity contingent upon involvement in counseling services but fosters greater shared decision-making. The revisions also relaxed the requirement that an OTP have a formal documented agreement with outside agencies; under Section 8.12(f)(1) the final rule calls for a ''documented agreement'' to provide such services.[74]

Further Consideration of Tribal Communities

Some commenters advocate for increased Tribal sovereignty by including Indian Tribes as potential Accreditation Bodies. Additionally, while the Indian Health Service is included in the list of exceptions for State law compliance, OTPs operated by Indian Tribes must also be included to align with Tribal sovereignty. Accordingly, when States or ''State law'' is referenced, they urge SAMHSA to also include Tribes or ''Tribal law''.

Another commenter communicates concern about lack of safe transportation and funding to access treatment on some Tribal reservations, institutionalized racism and marginalization, as well as lack of positive integration of American Indian/Alaska Native culture into treatment for those populations. The commenter indicates that it is vital that SAMHSA alter the rule to explicitly include addressing the needs of marginalized communities, including Tribes and Tribal entities.

Response: SAMHSA recognizes the need for culturally supportive care that addresses race, ethnicity, Tribal sovereignty, sexual orientation, religion and gender identity, and social determinants of health, such as housing and transportation, that may pose barriers to treatment engagement, or harm reduction and recovery support service needs. Patient-centered language in the NPRM was finalized in this rule to ensure that the care provided is consistent with the patient's needs, and self-identified goals for treatment and recovery. SAMHSA encourages OTPs serving American Indians and Alaska Natives to implement culturally competent and patient-centered care. SAMHSA notes that it and other agencies have developed resources that

[74] *See https://www.samhsa.gov/sites/default/files/dear-colleague-letter-fda-samhsa.pdf.*

may be helpful in developing culturally sensitive approaches for AI/AN populations.[75]

The Department has not included 'Tribal law' whenever 'State law' is referenced, as Tribal laws vary widely. Accordingly, understanding what the reference means, or its scope, in some situations may be ambiguous. Therefore, it would be inappropriate to include Tribal law in this context.

Intake

Commenters requested clarification on the application of the new intake rules under Section 8.12(f)(2). Some commenters requested that clarification include explicit descriptions of rule application to clinical scenarios such as care transitions from hospital or non-OTP settings to OTPs. Commenters were supportive of allowing non-OTP clinicians to complete the intake screening and full examinations to expedite access during this process, though some commentors specified that the OTP provider must later review and approve the exams completed outside of an OTP. Some commentors stated that more frequent regular medical exams may be helpful during the first year of treatment to ensure safety and efficacy of treatment. One commenter requested clarification as to whether the full physical exam includes a mental status exam or an assessment of psychiatric symptoms, due to the high incidence of such symptoms among these patients. Another commenter requested clarity as to whether methadone may be initiated during the 14-day grace period for full OTP intake and screening/full examination, as some State regulations interpret this differently.

Response: The final regulations, under Section 8.12(f)(2)(a), facilitate initial screening to allow for medication to commence at time of initial intake; SAMHSA recommends methadone medication induction not be delayed until the full examination is completed.[76] The purpose of the initial screening is to ensure that there are no contraindications to prescribing methadone; this may require a psychiatric screening or evaluation of psychiatric symptoms, if clinically indicated. If mental health is not assessed at the time of screening, it should be completed subsequently as part of the patient's assessment to identify any service needs. Proposed regulations were finalized as written, since they explicitly address these comments.

Commenters were concerned about the requirement to complete a psychosocial assessment within 14 days, stating that patients often experience instability at the time of entry into treatment, which makes this difficult; some commenters suggest providing 30 days to complete the assessment. One commenter also requested an exception be provided to ensure patients diagnosed with OUD are not excluded from MOUD because of documented failure or that only documentation of reasonable effort to complete this assessment is required. Another commenter adds that this short, prescriptive timeframe is not always conducive to developing therapeutic rapport between patients and providers and may force programs to be overly restrictive, disrupting patient engagement at a critical time.

Response: Patients entering treatment for OUD are often in crisis and this is the basis for the requirement that a complete psychosocial assessment be conducted within 14 days. This is especially important because the final rule allows patients new to treatment to receive up to 7 take-home doses of methadone. The psychosocial assessment informs part of the initial examination, and as such, it is the basis of continued assessment and management as indicated. There is no requirement for a definitive list of diagnoses to be created at this time. Rather, this is an opportunity to create a detailed plan of care which might include continued assessment and monitoring of psychosocial status. To facilitate timely completion of the assessment, the final rule includes flexibilities for the use of telehealth.

Serology Testing

For serology testing, comments recommend the patient should explicitly retain the right to refuse or defer testing unless the medical provider deems it necessary for patient safety. Others asked for clarification on the deadline (14-day or 30-day) stating that 8.12 (f)(2)(B)(iii) and (iv) as proposed appeared contradictory.

Response: An individual patient always has the right to refuse testing, and this provision therefore has been clarified in the final rule. Specifically at 8.12(f)(2)(i)(b), now states that a ''patient's refusal to undergo lab testing should not preclude them from access to treatment, provided such refusal does not have the potential to negatively impact treatment with medications''. In regard to the suggested 14-day or 30-day discrepancy, these timeframes refer to use of serology results: it is permissible to use serology results drawn no more than 30 days prior to admission to the OTP, or up to 14 days after admission to the OTP to complete the full examination. Thus, these two provisions are not inconsistent.

Treatment Discharge Concerns

Several comments expressed concern over removal of language in the proposed rule concerning discharge, asserting that this change removes important patient protections that have helped to promote humane discharge processes. Whether patients are discharged for nonpayment or other reasons, commenters emphasize that tapering schedules must be based on clinical and safety considerations.

Response: The importance of discharge planning has been highlighted in the final rule. Specifically, under Section 8.11(f)(2)(iv) discharge decisions have been enumerated to require a patient-centered approach. Such decisions must be documented, and planned in a manner that ensures, to the greatest extent possible, that patient treatment is not disrupted. Proposed language from the NPRM pertaining to discharge planning throughout Section 8.12 has been finalized.

Split Dosing

Numerous commenters support the expansion of split dosing for all OTP patients receiving take-home doses, defined in Section 8.2, based on the clinical judgement of the OTP practitioner, and urge SAMHSA to add language specifying that additional testing and submission of documentation for split dosing is unnecessary if the clinician has clearly documented in the medical record that split dosing will benefit the patient. Commenters also emphasize that take-home doses are essential for split dosing, especially for pregnant patients and patients driving long distances to receive medication.

Response: The final rule does not specify requirements of any additional testing or documentation beyond that of routine clinical practice. There is nothing in the final rule that precludes provision of split doses for take-home doses of methadone.

Dosage During Treatment Induction

At Section 8.12(h)(3)(ii) commenters emphasize that higher initial and next day doses are often clinically appropriate and necessary to prevent withdrawal and treatment attrition,

[75] *See https://www.samhsa.gov/behavioral-health-equity/ai-an.*

[76] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21–02–01–002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

especially for patients exposed to fentanyl, as well as for patients in the later stages of pregnancy, and that clinicians require more clarification on this. Commenters questioned whether the additional medication is administered as one higher dose or additional, incremental dose(s) at several hour interval(s). They worry that lack of clarity will result in underutilization and thus lower treatment retention. Some commenters suggest eliminating induction dosing guidelines (which they view as a reflection of longstanding stigma and discrimination against patients in OTP treatment). These commenters suggest entrusting these decisions to practitioners, noting that other medication dosage decisions for many medical conditions are left to judgment and discretion of medical providers. Some commenters also caution that higher induction doses must not be discouraged when medically necessary for efficacious treatment.

Response: A primary purpose of the final rule is to promote use of clinical judgement as well as patient-centered care. These comments speak to the need for ''shared decision-making'' in the practitioner-patient relationship, and the final rule supports this through empowering practitioners to work with patients to create individualized plans of care. Section 8.12(h)(3)(ii) has been clarified in a manner that does not prohibit higher induction doses, but requires the rationale for higher induction doses to be documented in the patient's record.

Audio-Only Telehealth

Commenters emphasize that audio-only telehealth is an important permanent provision for counseling and buprenorphine initiation to ensure more equitable access to OTPs.

Response: SAMHSA agrees with commenters that telehealth, including audio-only telehealth, can be an important tool to enhance access to treatment. SAMHSA also recognizes scientific evidence that further supports integration of telehealth provisions in the final rule consistent with clinical guidelines and safety requirements. The final rule accordingly states that in evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used at the patient and provider's preference. For schedule II medications (such as Methadone), the rule allows for audio-visual telehealth initiation by the OTP practitioner. When audio-visual technologies are not available or their use is not feasible for a patient, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. This is because, as noted, in the proposed rule, schedule II medications such as methadone pose increased risk compared to schedule III medications such as buprenorphine. In all cases, medications for the treatment of OUD shall be ordered by the OTP practitioner.

Audio/Visual Telehealth for Medical Intake and ''Annual Physical'' Appointments

Video-based telehealth, under section 8.12(f)(2)(B)(v), is overwhelmingly supported by commenters for medical intake, periodic medical assessments, and methadone or buprenorphine initiation by OTP practitioners. Onsite staff can supplement telehealth care by gathering vital sign and toxicology data, when necessary. One comment questioned if any appropriate limits, for example on the number of patients a single physician could oversee via telehealth should be added.

Response: SAMHSA appreciates these comments and has finalized proposed changes in the final rule. Requirements pertaining to telehealth, including the number of patients that a practitioner may see, are governed by applicable State and Federal laws. As noted above, however, provisions in this final rule support use of telehealth as part of patient treatment.

Take-Home or Unsupervised Doses

Provisions expanding take-home or unsupervised methadone medication doses, under Section 8.12(i), are mostly supported, with commenters citing increased patient autonomy and pride, improved outcomes and treatment retention, and reduced barriers to treatment. The removal of the eight take-home criteria is accordingly supported by some, though others note that toxicology testing is important to help maintain public and patient safety. Some commenters expressed concern about potentially increased diversion, while another commented that diversion is a sign of unmet community need and should be addressed as such, rather than criminalized. Some commenters worried that the revised take-home allowances are too flexible and some proposed different guidelines; others supported them or even wanted them eliminated entirely, trusting providers with that responsibility. Yet, other commenters worried that leaving decisions about take-homes completely to the discretion of providers could result in provider abuse and suggested that some parameters are necessary.

Many commenters expressed frustration that not all patients receive equitable access to take-homes, whether for insurance reasons or lack of clinic/state implementation. Some commenters suggest the addition of take-home metrics during the OTP survey process to help address this. Another commenter suggested SAMHSA provide a method of recourse for patients dissatisfied with decisions made about their take-home eligibility. One commenter requested clarification on insurance coverage of take-home doses, specifically with Medicare or Medicare Part D. One commenter asked that SAMHSA end the requirement for requested program exceptions when closing or dispensing extra take-home doses for weather emergencies and state holidays, and that patient suitability documentation for days the clinic is closed is only required for patients denied take-home medication.

Response: SAMHSA recognizes that its proposed provisions concerning take-homes were significant. Proposed changes have been finalized without alteration. While this approach promotes practitioner discretion, determining risk factors and preventing diversion has required team input since the original regulations were promulgated over 20 years ago.

A standard for treatment that is common to all Accreditation Bodies is that OTPs have policies regarding patient complaints and procedures that protect patients from retaliation. SAMHSA requires that Accreditation Bodies have policies and procedures in place to respond to complaints received from the Secretary, patients, facility staff, and others. Therefore, patients who have complaints about take-homes shall have access to recourse through required patient complaint and grievance procedures.

Determinations about insurance coverage and reimbursement for MOUD, while important, are outside the scope of this rulemaking.

Need for More Data

Several commenters expressed an ongoing need for more data to ensure treatment changes (such as additional take-home medication doses, induction dosing schedules, expansion of the definition of a qualified provider) are safe, especially post COVID–19 public health emergency (PHE) as circumstances and environments change. Some had concerns that changes provided too much flexibility,

especially with respect to take-home doses during the first week(s) of treatment, due to less patient stability/functionality during this transitional period. Others mentioned that patients might handle medications differently outside of the COVID–19 PHE environment, due to lack of behavior-modifying factors present during the PHE, such as isolation and fear for continued treatment. Other commenters expressed the need for more data related to induction dosing and best practices for rapid induction to effective doses while minimizing risk.

Response: Data is important to performance monitoring and evaluations of health care interventions. Accreditation standards require that OTPs have quality assurance systems that consider patient outcomes. The data related recommendations noted in these comments are items that could be incorporated into the OTPs quality assurance processes. These recommendations are better addressed in the revision of the Federal OTP guidelines that SAMHSA will complete following this rulemaking. SAMHSA and its partners, including the Centers for Disease Control and Prevention, FDA and National Institutes of Health (NIH), support further research on these issues, and SAMHSA will monitor the impact of this rule. As one example, FDA, SAMHSA and the Reagan-Udall Foundation held a meeting in May 2023 regarding 'Considerations for Buprenorphine Initiation and Maintenance Care' to ''explore real-world experiences and scientific evidence for buprenorphine initiation strategies as well as medication dosing and management during continued treatment across different care settings.'' [77] SAMHSA and NIH similarly collaborate to support the Helping to End Addiction Long-term® Initiative which focuses on improving pain treatment and developing community-level solutions to opioid addiction.[78] SAMHSA will continue on its own and with other agencies and stakeholders to explore and support research on these issues.

Pregnancy Testing

Several commenters advised against requiring pregnancy testing, under Section 8.12(f)(B)(iii), for pregnant OTP patients. They reasoned that, in a time when States are increasingly restricting and even criminalizing reproductive options, pregnancy testing may dissuade patients of child-bearing potential from seeking treatment.

Response: Pregnancy testing is often necessary for appropriate clinical care, and the final rule clarifies that pregnancy testing should be requested only when clinically appropriate, and that refusal of such testing should not preclude access to treatment. Safeguarding patient privacy and health is essential, and in all cases, providers must adhere to State and Federal laws and regulations, clinical requirements and professional guidelines when considering screening and disclosure of testing results. For instance, the 2015 'American College of Obstetricians and Gynecologists policy on Alcohol Abuse and Other Substance Use Disorders: Ethical Issues in Obstetric and Gynecologic Practice', emphasizes the importance of patient informed consent for testing.[79]

Ramifications of Dependency Diagnosis

One commenter expressed concern that under Section 8.12(f)(2), all patients receiving opioids must be documented in the medical chart with an opioid dependence diagnosis, even if the patient is a pain patient and the doctor has no dependency concerns. One commenter is concerned that this could affect eligibility for future organ transplants.

Response: These regulations establish the procedures by which the Secretary of HHS determines whether a program is qualified to dispense methadone and other medications in the treatment of opioid use disorders and standards regarding the use of these medications for treatment purposes, in accordance with the Controlled Substances Act (CSA) under 21 U.S.C. 823(h). As a result, a diagnosis of opioid use disorder is required. SAMHSA notes that opioid dependence is an older diagnostic term that, in the U.S., has been replaced with the diagnostic term of opioid use disorder and associated diagnostic criteria. Proposed changes, as written, were finalized in the rule.

Protecting Patient Data

Central registries are often queried to detect and prevent potential multiple enrollments in more than one OTP. Central registries are briefly described in 42 CFR part 2 (Confidentiality of Substance Use Disorder Patient Records) regulations, but one commenter is concerned that there do not appear to be limits on their collection and sharing of sensitive patient information and requests regulations better clarify appropriate practices.

Response: Central registries are State-based operations. Although the patient information is protected, procedures for assuring protection and relevant regulations such as 42 CFR part 2 and the Health Insurance Portability and Accountability Act are outside the scope of these Part 8 regulations.

Alignment of State and Federal Guidelines

There were many commenters that expressed concerns with State regulations as they intersect with proposed SAMHSA changes. If States have more restrictive regulations, especially related to medication administration, for instance, then patients in those States may not benefit from Federal changes, some commenters asserted. These commenters urged that States be required to align with Federal regulations, even if it means withholding funds to States who refuse to adopt new Federal regulations. Some commentors also requested language be added mandating State Opioid Treatment Authorities (SOTAs) are included in communications such as when and how an OTP is not meeting standards, withdrawal of approval of Accreditation Bodies, and others.

Response: These rules do not mandate that States promulgate less restrictive rules to match provisions of Federal law that may provide more flexibility. SAMHSA works closely and collaboratively with the SOTAs and State mental health and substance use disorder treatment authorities, the Accreditation Bodies, as well as other Federal agencies to encourage State and Federal alignment and information-sharing.

Other Themes

There were two comments that urged keeping Levomethadyl acetate (LAAM) on the list of approved treatment medications. These comments suggested that research could indicate it is an effective treatment for opioid use disorder and that it may soon be available for use again. Additionally, other comments advocated integration of other FDA-cleared treatment options like neuromodulation and other medical technology.

Response: Currently, LAAM is not available in the United States. For this reason, it was removed from the list of currently approved and available medications for OUD. The list provided in the rule is current, and there is nothing that precludes changes to the list of medications used to treat OUD in the future. Technology is not currently

[77] *See https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care.*

[78] *See https://heal.nih.gov/.*

[79] *See https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/06/alcohol-abuse-and-other-substance-use-disorders-ethical-issues-in-obstetric-and-gynecologic-practice.*

addressed in 42 CFR part 8 as devices and available applications are an adjunct to treatment with MOUD. SAMHSA will monitor the development and approval of new medical devices by FDA for the treatment of chronic opioid use disorder and will consider updates to part 8 as needed.

E. Summary of the Final Rule

The Department has finalized the following changes to 42 CFR part 8 that revise, delete, replace, or add sections. This section summarizes changes in the final rule, and discusses changes made after review of public comments on the NPRM entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330), and the SNPRM entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA–2000 Waiver Requirements' (88 FR 9221).

1. Title

The Department has finalized the title, originally proposed in the NPRM, as being: *Medications for the Treatment of Opioid Use Disorder.* As discussed in the NPRM, this title reflects current medical terminology and removes stigmatizing language. The term 'opioid use disorder' more precisely reflects the diagnosis for which medications are indicated. Further to this, the terms 'maintenance' and 'detoxification' reference outdated terminology that has potentially hindered adoption of evidence-based treatments for OUD.[80] The amended title reflects current medical terminology and highlights that OUD is a chronic, treatable condition.

2. Subpart A

Reorganization of subpart A, as proposed in the NPRM and SNPRM, has been finalized and includes the scope and definitions.

3. Section 8.1—Scope

Pursuant to the NPRM and SNPRM, § 8.1 is finalized to reflect modern medical terminology, to detail updated acronyms, and for clarity. Of note, the term medication assisted treatment (MAT) has been updated to medications for opioid use disorder (MOUD), and the term treatment program has been changed to opioid treatment program throughout the final rule. Pursuant to proposed changes set forth in the SNPRM entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA–2000 Waiver Requirements' (88 FR 9221), reference to subpart F has been removed.

4. Section 8.2—Definitions

Changes proposed by the NPRM and SNPRM have been finalized in § 8.2 to add, remove and update definitions. Added definitions include: care plan; harm reduction; individualized dose; long-term care facility; recovery support services; split dosing; and telehealth. Existing definitions updated include: comprehensive treatment; medication for opioid use disorder; and practitioner. The term detoxification treatment is removed and replaced with withdrawal management. Definitions for additional credentialing, approval term, covered medications, and emergency situation have been removed.

5. Section 8.3—Application for Approval as an Accreditation Body

Changes proposed by the NPRM are finalized to include details of policies and procedures expected of Accreditation Bodies, particularly that Accreditation Bodies shall include staff physician(s) with experience in treating OUD with MOUD in their survey team. Furthermore, this regulation is updated, pursuant to the NPRM, to ensure that Accreditation Bodies provide training policies specifically related to training of survey team members. As described in the NPRM, the final rule also provides for Indian Tribes, in addition to State or territorial governments, to apply for approval as an Accreditation Body.

6. Section 8.4—Accreditation Body Responsibilities

In response to public comments, language that clarifies SAMHSA's oversight of Accreditation Bodies, and associated expectations, has been updated and finalized. To this end, the Department has provided clarification on the steps to be taken by Accreditation Bodies in response to OTPs that are found to not be complying with accreditation or certification standards, such as follow up on corrective measures and confirmation of timely corrections. In particular, section 8.4(b) of the final rule includes: provisions requiring categorization of the types of non-compliance; provisions that differentiate between accreditation duration based on the severity of non-compliance; and adds provisions detailing procedures for severe non-compliance. Time frames for submission of survey reports are also finalized. Pursuant to the NPRM, the Department has finalized the requirement that all records of accreditation activities be made available to SAMHSA upon request. Current requirements regarding Accreditation Body follow up on complaints are maintained but, as per the NPRM, the final rule adds a requirement that Accreditation Bodies notify SAMHSA of all aspects of a complaint response within 5 days of receipt. Similarly, the previous rule requiring surveyors to recuse themselves from surveys due to conflict of interest is amended to clarify that such conflicts must be documented by the Accreditation Body and made available to SAMHSA.

7. Section 8.11—Opioid Treatment Program Certification

This section is finalized, pursuant to the NPRM, to update categories of certification, to clarify the requirement that OTPs maintain certification, and to establish procedures for OTPs whose certification has lapsed. Terms for the extension of certification are finalized, as are the means of requesting an extension. The final rule also updates the certification application process to reflect the shift from paper applications to electronic submission, and the email address for submission of supporting documents is corrected.

As described in the NPRM, the final rule removes ''Transitional certification'' which expired as a category of certification in 2003. Further, the wording of ''Provisional certification'' is amended to clarify that it is a category of certification available only to new programs that have not been previously certified, and a new category of ''Conditional Certification'' has been added for OTPs that have received a one-year conditional accreditation status from an Accrediting Body—an organization that has been approved by the Secretary of HHS to accredit OTPs—in order for operations to continue or resume as the OTP takes steps needed to achieve permanent certification. The criteria for granting certification extensions outside of routine certification renewals has been expanded to address extensions needed under extraordinary circumstances. The grammar used in describing procedures for requesting an extension was revised.

The applicability of Health Insurance Portability and Accountability Act (HIPAA) privacy protections have been explained, along with clarification that changes in the status of the program sponsor or medical director must be submitted to SAMHSA in writing.

Pursuant to the NPRM, the conditions for approval of interim treatment have been finalized to increase the duration of interim treatment from 120 days to 180 days, with the stipulation that

[80] NIDA. 2021, November 29. Words Matter—Terms to Use and Avoid When Talking About Addiction. Retrieved from *https://nida.nih.gov/nidamed-medical-health-professionals/health-professions-education/words-matter-terms-to-use-avoid-when-talking-about-addiction.*

individuals shall not be discharged without the approval of an OTP practitioner while awaiting transfer to a comprehensive treatment program. In response to public comments on the NPRM, availability of interim treatment is also expanded to all OTPs. For clarity, reference to section 1923 of the Public Health Service Act (21 U.S.C. 300x–23) is removed. The NPRM and final rule also shifts the need to seek approval from the 'chief public health officer' of the State in which the OTP operates to the State Opioid Treatment Authority in the State in which the OTP operates.

As described in the NPRM, the services that can be provided in medication units have been finalized to explicitly allow the full range of OTP services, based on space and privacy available in the medication unit.

8. Section 8.12—Federal Opioid Use Disorder Treatment Standards

Revisions of treatment standards, as described in the NPRM, are finalized in order to improve access to treatment, improve patient satisfaction and engagement in services and support use of clinical judgment in decision-making. In several instances, stigmatizing language such as ''legitimate treatment use'' of controlled medications, has been removed and patient-centered language is added.

The paragraph on staff credentials, found in the NPRM, is finalized to expand the definition of a practitioner to a ''a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP.'' The expectation that all licensed and credentialed staff maintain licensure and/or certification has been finalized.

Criteria for admission to treatment, as discussed in the NPRM, removes reference to the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV and eliminates the requirement for a one-year history of OUD. Instead, the final rule specifies that the individual should either: meet diagnostic criteria for active moderate to severe OUD; that the individual may be in OUD remission; or at high risk for recurrence or overdose. The section is finalized to ensure that the basis for the admission decision is documented in the patient's record. In recognition of the use of telehealth and its limitation in obtaining physical signatures, the requirement to obtain written patient consent to treatment is altered to the extent that consent may be provided verbally or electronically, and documented as such. The requirement that individuals under age 18 have two documented unsuccessful attempts at short term withdrawal management (''detoxification'') or drug free treatment is also finalized so to allow consent of a parent, legal guardian, or responsible adult. Further to this, the rule requiring a 1-year history of OUD for people recently released from correctional settings, pregnant patients or previously enrolled individuals has been removed.

Throughout the document, as described in the NPRM, ''detoxification'' and the corresponding definition and standards for short-and long-term detoxification treatment have been removed. ''Withdrawal management'' and terms for tapering from MOUD are added on behalf of individuals who seek this approach or who elect or need to reduce and/or discontinue MOUD.

The paragraph on ''Required services'' is finalized to incorporate patient-centered language, establish flexible terminology, promote use of clinical judgment, and clarify SAMHSA's expectations of OTPs. The final rule creates the requirement that services be available that meet patient needs, and ''shared decision making'' is added as the method to be used in developing care plans.

The paragraph describing the initial medical examination has been finalized, pursuant to the NPRM, to clarify the terms ''screening'' medical exam and ''comprehensive examination'', while also expanding the qualifications of practitioners able to complete such examinations. These include practitioners outside of the OTP (with limitations and specific instructions). The final rule also creates criteria for lab testing conducted prior to a screening medical exam, as well as a permissible timeframe. The use of telehealth in undertaking the screening medical exam and initiation of MOUD at the OTP, by the OTP practitioner, has also been finalized in the rule. Additionally, the paragraph on special services for pregnant people is finalized to specify that confirmation of pregnancy should be requested for priority treatment admissions. The option to use split dosing for patients, as described in the NPRM, is also finalized.

The components of initial and periodic medical examinations have been finalized, pursuant to the NPRM, to incorporate assessment of behavioral health, risk of self-harm or harm to others, and to specify time frames for completion of the care plan. Areas of psychosocial assessment are finalized so as to assure information is gathered in the context of the patient's whole life such as their mental health, housing, recovery support and harm reduction resources. Additionally, patient-centered language has been finalized, such as ''services a patient needs and wishes to pursue''.

The final rule expands the provision of 'counseling services' that are provided by OTPs to include psychoeducational services, harm reduction and recovery-oriented services, and counseling and linkage to treatment for anyone with positive test results on human immunodeficiency virus (HIV), viral hepatitis, and other sexually transmitted infection (STI) panels, or from OTP-provided medical examinations. Language about services that must be provided directly or through referral is finalized to promote a patient-centered approach to care that does not make medication continuity contingent upon involvement in counseling services but fosters shared decision-making for all care plans.

The requirement that an OTP have a formal documented agreement with outside agencies is finalized to remove the word ''formal''; the final rule calls for a ''documented agreement'' to provide such services.

Language that addresses drug testing services has been finalized to remove stigmatizing phrases, such as ''drug abuse'', and to remove content on short-term withdrawal management (''detoxification''). Further to this, the final rule clarifies that the requirement to use drug tests that have received the Food and Drug Administration (FDA)'s marketing authorization is limited to random drug testing using samples obtained from patients, including urine or saliva. Pursuant to public comments on the NPRM, the final rule does not preclude distribution of legally permissible testing supplies, that check for adulteration of an individual's personal drug supply.

Rules that address recordkeeping and efforts to avoid simultaneous enrollment in multiple OTPs are finalized, as per the NPRM, to be more declarative, such as changing the word ''review'' to ''determine'' whether or not a patient is enrolled in another OTP, and documenting review efforts in the patient's record to demonstrate the good faith efforts made. The final rule also expands the circumstances in which a patient may obtain treatment at another OTP to include instances when there is an inability to access care at the OTP of record.

As described in the NPRM, specification of disciplines authorized to administer or dispense MOUD is removed from the final rule. LAAM, also known as Levomethadyl acetate, is removed from the list of treatment

medications because it is no longer available, and other medications approved since prior revisions to this rule were added. In response to public comments, the regulation of an initial dose of methadone has been increased to 50mg on the first day, with the clarification of allowance for higher doses if clinically indicated, and documented in the patient's record. The rule to ensure documentation of any significant deviation from FDA-approved labeling has been maintained in the final rule, while redundant language was removed.

Rules on the provision of unsupervised (or take-home) doses of methadone are finalized, as per the NPRM, to incorporate flexibilities issued in response to the COVID–19 pandemic. In general, the final criteria allow up to 7 days of take-home doses during the first 14 days of treatment, up to 14 take-home doses from 15 days of treatment and up to 28 take-home doses from 31 days in treatment. The requirement that OTPs maintain procedures to protect take-homes from theft and diversion is finalized, as well as patient education on safe transport and storage of take-home doses, including documentation of the provision of this education in the patient's clinical record.

Consistent with the conditions for approval of interim treatment, the final rule extends the potential duration of interim treatment from 120 days to 180 days. It also clarifies the circumstances in which interim treatment may apply and maintains priority access to comprehensive services for pregnant individuals. The rule finalizes removal of the requirement for observation of all daily doses during interim treatment. It also finalizes the expectation that crisis services and information pertaining to locally available, community-based resources for ancillary services be made available to individual patients in interim treatment. A requirement of a plan for continuing treatment beyond 180 days of interim services is also finalized.

9. Section 8.13—Revocation of Accreditation and Accreditation Body Approval

References to an OTP as a ''program'' instead of a ''facility'' are finalized.

10. Section 8.14—Suspension or Revocation of Certification

Pursuant to the NPRM, this section finalizes the actions that SAMHSA may take when immediate intervention is necessary to protect the public's health or safety. The final rule specifies the administrative actions available to SAMHSA in the event that a program sponsor, or any employee of an OTP has: been found to have engaged in misrepresentation in obtaining certification; failed to comply with the Federal Opioid Use Disorder treatment standards; failed to comply with reasonable requests from SAMHSA or from an Accreditation Body for records; or refused a reasonable request of a duly designated SAMHSA inspector, DEA Inspector, State Inspector, or Accreditation Body representative for permission to inspect the program or the program's operations or its records.

11. Subpart D—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

References to an OTP as a ''program'' instead of a ''facility'' are finalized.

12. Subpart F—Authorization To Increase Patient Limit to 275 Patients

This subpart and corresponding sections are removed from the final rule, as described in the SNPRM.

Severability

The Department asserts that provisions in this final rule are severable. If any provision of this rule, or the application thereof to any person or circumstance is held invalid, that invalidity shall not affect other provisions or applications of this rule that can be given effect without the invalid provision or application.

This rule has been organized in a way that separates out the major provisions into distinct sections and subparts. Many of the provisions in this rule are independent of each other and could function sensibly even without certain other provisions being in effect. For example, the provisions in subparts A, B and C related to accreditation and certification are distinct from the Treatment Standards enumerated in subpart C section 8.12. Rules related to take-home dosing of methadone are also severable from other rules, such as those regarding telehealth and interim treatment.

If any specific provision of this rule is found unconstitutional or invalid, the Department intends that the remainder would still operate independently. The Department believes that each provision in this rule offers a distinct benefit to the public, patients, and healthcare providers. Therefore, if any specific application or provision is invalidated, the remainder of the legally valid provisions should remain in effect.

Regulatory Impact Analysis

The Department has examined the impact of the final rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (October 4, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (January 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (August 10, 1999); Executive Order 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (November 9, 2000); Executive Order 13985 Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009 (January 25, 2021); the Congressional Review Act, Public Law 104–121, sec. 251, 110 Stat. 847 (March 29, 1996); the Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat.48 (March 22, 1995); the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (September 19, 1980); Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (August 16, 2002); the Assessment of Federal Regulations and Policies on Families, Public Law 105–277, sec. 654, 112 Stat. 2681 (October 21, 1998); and the Paperwork Reduction Act of 1995, Public Law 104–13, 109 Stat. 163 (May 22, 1995).

Statement of Need

This final rule is being issued to update part 8 in response to increasing opioid overdose deaths, exacerbated by the COVID–19 pandemic.[81] Across the United States in 2021, 9.2 million people aged 12 or older misused heroin or misused prescription pain relievers in the preceding twelve months.[82] The percentage was highest among young adults aged 26 or older (3.5 percent or 7.7 million people), followed by adults aged 18 to 25 (3.1 percent or 1 million people). It was lowest among adolescents aged 12 to 17 (1.9 percent

[81] Cartus AR, Li Y, Macmadu A, Goedel WC, Allen B, Cerdá M, Marshall BDL. Forecasted and Observed Drug Overdose Deaths in the US During the COVID–19 Pandemic in 2020. JAMA Netw Open. 2022 Mar 1;5(3):e223418. doi: 10.1001/jamanetworkopen.2022.3418. PMID: 35311967; PMCID: PMC8938716.

[82] Substance Abuse and Mental Health Services Administration. (2022). Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22–07–01–005, NSDUH Series H–57). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. *https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report.*

or 497,000 people).[83] These numbers likely underestimate the true prevalence of opioid misuse and opioid use disorder (OUD), since the use of illicitly manufactured fentanyl has not to date been considered in the National Survey on Drug Use and Health (NSDUH), and populations likely to have high prevalence of opioid misuse and use disorder, such as individuals in the criminal justice system, other institutionalized settings, and individuals experiencing homelessness and not living in shelters, are not included in the NSDUH.

Further to this, there are important equity considerations evidenced by the data. A recent analysis by the Centers for Disease Control and Prevention (CDC) demonstrates high levels of overdose among non-Hispanic Black, American Indian and Alaska Native communities over the course of the pandemic.[83] This study showed that overdose death rates rose 44 percent in 2020 for Black people and 39 percent for American Indian and Alaska Native people, compared with 22 percent for white people.[83] Black youth ages 15 to 24 saw an 86 percent increase in overdose deaths, the largest spike of any age or race group, while Black men 65 and older were nearly seven times as likely than white men to die from an overdose.[83] It was also found that Black people were less than half as likely as white people to have received substance use treatment. As SAMHSA has noted, the Hispanic community also has been adversely impacted by opioid overdoses.[84]

Research demonstrates that MOUD can reduce mortality from overdose by up to 59% (based on results of multivariable Cox proportional hazards models adjusted for age; sex; baseline anxiety diagnosis; depression diagnosis; receipt of methadone, buprenorphine, opioid, and benzodiazepine prescriptions in the 12 months before index nonfatal opioid overdose; and time-varying receipt of opioid prescriptions, benzodiazepine prescriptions, withdrawal management episode, and short- and long-term residential treatments),[85] yet few people who may benefit from these medications have immediate and sustained access to them.[86]

The pattern of enrollment in programs providing methadone was established in the latter part of the 20th century.[87] Research reveals that the rate of methadone treatment at that time was highest in low-income urban areas.[88] These patterns have remained relatively unchanged since the expansion of access to buprenorphine in 2002. Research demonstrates that there are extensive 'treatment deserts' where there is little to no physical access to OTPs, especially in rural areas.[89] SAMHSA believes that changes to part 8 will, as described above, facilitate:

- Enhanced access to medications for opioid use disorder, such as through take-home doses of methadone and extending interim treatment to 180 days;
- Reduced stigma and discrimination based on changes to ensure updated language and terminology;
- Clarification of standards applying to Accreditation Bodies; and
- Revising Federal Opioid Use Disorder Treatment Standards.

SAMHSA notes below that these changes are associated with limited burden as the final rule does not substantially alter reporting or accreditation activities. The changes will support SAMHSA in its role of overseeing Accrediting Bodies and OTPs, modernizing language and expectations in response to current challenges and anticipated future trends.

A. Executive Orders 12866 and 13563 and Related Executive Orders on Regulatory Review

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to, and reaffirms the principles, structures, and definitions governing regulatory review as established in, Executive Order 12866.

This final rule is partially regulatory and partially deregulatory. The Department estimates that because much of what has been finalized does not substantially alter current practice as implemented over the past 3 years under the COVID PHE, the final rule will not result in significantly altered costs. Further to this, the final rule creates efficiencies in service delivery and in administration. These include strengthening the patient-practitioner relationship in a manner that promotes efficient, evidence-based and patient-centered care, updating accreditation procedures and providing a stable regulatory environment. Additionally, the final rule makes permanent some OTP treatment flexibilities implemented within the past three years.

B. Executive Order 13985 Advancing Racial Equity and Support for Underserved Communities Through the Federal Government

A recent analysis by the Centers for Disease Control and Prevention (CDC) demonstrates high levels of overdose among Black, American Indian and Alaska Native communities over the course of the pandemic.[90] While these trends existed long before the COVID–19 PHE, this study highlights that overdose death rates rose 44 percent in 2020 for Black people and 39 percent for American Indian and Alaska Native people, compared with 22 percent for white people.[91] Black youth ages 15 to 24 saw an 86 percent increase in overdose deaths, the largest spike of any

[83] Kariisa M, Davis NL, Kumar S, et al. Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics—25 States and the District of Columbia, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:940–947. DOI: *http://dx.doi.org/10.15585/mmwr.mm7129e2*. See also *https://www.seattletimes.com/nation-world/nation/addiction-treatment-medicine-is-vastly-underprescribed-especially-by-race-study-finds/*.

[84] Substance Abuse and Mental Health Services Administration: The Opioid Crisis and the Hispanic-Latino 1opulatiorgent Issue. Publication No. PEP20–05–02–002. Office of Behavioral Health Equity. Substance Abuse and Mental Health Services Administration, 2020. *https://store.samhsa.gov/sites/default/files/pep20-05-02-002.pdf*.

[85] Larochelle MR, Bernson D, Land T, Stopka TJ, Wang N, Xuan Z, Bagley SM, Liebschutz JM, Walley AY (2018). Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality: A Cohort Study. Ann Intern Med. Aug 7;169(3):137–145. doi: 10.7326/M17–3107.

[86] Winograd RP, Presnall N, Stringfellow E, Wood C, Horn P, Duello A, Green L, Rudder T. (2019). The case for a medication first approach to the treatment of opioid use disorder. Am J Drug Alcohol Abuse. 2019;45(4):333–340. doi: 10.1080/00952990.2019.1605372. Epub 2019 May 14. PMID: 31084515.

[87] D'Aunno T, Pollack HA. (2002). Changes in methadone treatment practices: results from a national panel study, 1988–2000. JAMA. 2002;288(7):850–856. doi:10.1001/jama.288.7.850.

[88] Strain EC, Stitzer ML, Liebson IA, Bigelow GE. (1994). Comparison of buprenorphine and methadone in the treatment of opioid dependence. Am J Psychiatry. 1994 Jul;151(7):1025–30. doi: 10.1176/ajp.151.7.1025. PMID: 8010359.

[89] Mitchell P, Samsel S, Curtin KM, Price A, Turner D, Tramp R, Hudnall M, Parton J, Lewis D. (2022). Geographic disparities in access to Medication for Opioid Use Disorder across US census tracts based on treatment utilization behavior. Soc Sci Med. 2022 Jun;302:114992. doi: 10.1016/j.socscimed.2022.114992. Epub 2022 Apr 28. PMID: 35512612.

[90] Kariisa M, Davis NL, Kumar S, et al. Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics—25 States and the District of Columbia, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:940–947. DOI: *http://dx.doi.org/10.15585/mmwr.mm7129e2*.

[91] Krawczyk, N., Rivera, B.D., Levin, E., & Dooling, B.C.E. (2023). Synthesizing evidence of the effects of COVID–19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. The Lancet. Public health, 8(3), e238–e246. *https://doi.org/10.1016/S2468-2667(23)00023-3*.

age or race group, while Black men 65 and older were nearly seven times as likely than white men to die from an overdose.[90] It was also found that Black people were less than half as likely as white people to have received substance use treatment.

This disparity amplifies the importance of promoting patient-centered care that is culturally appropriate and responsive to patient need, while also fostering a treatment environment that promotes and sustains patient engagement. The final rule facilitates the practitioner-patient relationship in a manner that espouses these principles, while also expanding the reach of OTPs (through activities such as mobile medication units) to physically engage communities that are in need of intervention. Further to this, the final rule promotes examination of a patient's cultural needs as they engage in treatment services. This is consistent with evidence-based and culturally responsive paradigms of care.

The final rule also facilitates patient engagement through removing, at the practitioner's discretion, the requirement to attend an OTP each day. Indeed, the ability to provide unsupervised doses of methadone early in treatment allows those with unstable access to transportation, for example, to focus on recovery activities in their own community. Evidence from the past three years demonstrates safety, as well as high patient and practitioner satisfaction with take-home doses of methadone.[91] This is principally because take-home doses of methadone allow individuals the opportunity to engage in employment, education and other activities that are supportive of recovery and longer-term community involvement.

1. Cost-Benefit Analysis

a. Overview

The U.S. estimated economic cost of opioid use disorder ($471 billion) and fatal opioid overdose ($550 billion), prior to the pandemic, totaled $1,021 billion.[92] Among the 39 jurisdictions reviewed in this analysis, combined costs of opioid use disorder and fatal opioid overdose varied from $985 million in Wyoming to $72.6 billion in Ohio. Per capita combined costs varied from $1,204 in Hawaii to $7,247 in West Virginia. States with high per capita combined costs were located mainly in the Ohio Valley and New England. Across many studies, reduced quality of life is the largest component of the cost of opioid use disorder.[93]

A recent study showed that in the absence of treatment, 42,717 overdoses (4,132 fatal, 38,585 nonfatal) and 12,660 deaths were estimated to occur in a cohort of 100,000 patients over 5 years.[94] An estimated reduction in overdoses was associated with methadone treatment (10.7%), buprenorphine or naltrexone treatment (22.0%), and medication treatment combined with psychotherapeutic interventions (range, 21.0%–31.4%).[95] Estimated decreased deaths were associated with treatment with methadone (6%), buprenorphine or naltrexone (13.9%), and the combination of medications and psychotherapy (16.9%). When criminal justice costs were included, all forms of MOUD (with buprenorphine, methadone, and naltrexone) were associated with cost savings compared with no treatment, yielding savings of $25,000 to $105,000 in lifetime costs per person.

McAdam-Marx et al. reported in 2010 that Medicaid beneficiaries with opioid use disorder, physical dependence on opioids, or poisoning had nearly triple the total medical costs adjusted for baseline sample characteristics compared to beneficiaries matched by age, gender, and state with no opioid misuse diagnosis ($23,556 vs. $8,436; P <0.001).[95] The opioid dependence/abuse group (using an older version of the Diagnostic and Statistical Manual of Mental Disorders) also had higher prevalence of comorbidities, such as psychiatric disorders, pain-related diagnoses, and other substance use conditions. While this study considered overall cost, it did not address medication costs in particular, or any impact treatment may have had on overall cost.

OTPs provide comprehensive interventions including medications, counseling and services designed to offer a whole-person approach to care and ameliorate social determinants of health that contribute to substance misuse. Numerous studies have demonstrated that treatment with pharmacotherapy and counseling services can reduce overall healthcare costs for patients with OUD.[96] [97] [98] For example, a 2019 analysis demonstrated that a comprehensive approach to OUD treatment is associated with improved health and economic outcomes.[99] This study assessed patients with OUD treated at a comprehensive primary care center (CCP) and other Maryland facilities in a large State Medicaid program and demonstrated cost savings with a comprehensive approach to care. Compared to the non-CCP patient group (n = 867), the CCP group (n = 131) had a higher 6-month buprenorphine treatment retention rate (P <0.001), fewer hospital stays in the 12-month follow-up period (P = 0.005), and lower total cost (US$10,942 vs. $13,097, P <0.001) and hospital stay cost (US$1,448 vs. $4,265, P = 0.001).[100] Other measures, including emergency department utilization and cost, substance use-related cost, and non-buprenorphine pharmacy cost, were not statistically different between the 2 groups. Results suggested that patients, as well as the health care system, can benefit from a comprehensive model of care for OUD with better treatment

[92] Luo, F., Li, M., & Florence, C. (2021). State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose—United States, 2017. MMWR. Morbidity and mortality weekly report, 70(15), 541–546. *https://doi.org/10.15585/mmwr.mm7015a1.* See also *https://trumpwhitehouse.archives.gov/briefings-statements/cea-report-underestimated-cost-opioid-crisis/* citing a Council of Economic Advisors study estimating 2015 costs at $504 billion and a Congressional study using the CDC methodology estimating 2020 opioid crisis costs as $1.5 trillion. See *https://beyer.house.gov/news/documentsingle.aspx.*

[93] Mitchell, S.G., Gryczynski, J., Schwartz, R.P., Myers, C.P., O'Grady, K.E., Olsen, Y.K., & Jaffe, J.H. (2015). Changes in Quality of Life following Buprenorphine Treatment: Relationship with Treatment Retention and Illicit Opioid Use. Journal of psychoactive drugs, 47(2), 149–157. *https://doi.org/10.1080/02791072.2015.1014948.*

[94] Fairley M, Humphreys K, Joyce VR, et al. (2021). Cost-effectiveness of Treatments for Opioid Use Disorder. JAMA Psychiatry. 2021;78(7):767–777. doi:10.1001/jamapsychiatry.2021.0247.

[95] McAdam-Marx C, Roland CL, Cleveland J, Oderda GM (2010). Costs of opioid abuse and misuse determined from a Medicaid database. J Pain Palliat Care Pharmacother. 2010 Mar;24(1):5–18. doi: 10.3109/15360280903544877. PMID: 20345194.

[96] Murphy SM, Polsky D (2016). Economic Evaluations of Opioid Use Disorder Interventions. Pharmacoeconomics. 2016 Sep;34(9):863–87. doi: 10.1007/s40273–016–0400–5. PMID: 27002518; PMCID: PMC5572804.

[97] Baser O, Chalk M, Fiellin DA, Gastfriend DR (2011). Cost and utilization outcomes of opioid-dependence treatments. Am J Manag Care. 2011 Jun;17 Suppl 8:S235–48. PMID: 21761950.

[98] Lynch FL, McCarty D, Mertens J, Perrin NA, Green CA, Parthasarathy S, Dickerson JF, Anderson BM, Pating D (2014). Costs of care for persons with opioid dependence in commercial integrated health systems. Addict Sci Clin Pract. 2014 Aug 14;9(1):16. doi: 10.1186/1940–0640–9–16. PMID: 25123823; PMCID: PMC4142137.

[99] Hsu, Y.J., Marsteller, J.A., Kachur, S.G., & Fingerhood, M.I. (2019). Integration of Buprenorphine Treatment with Primary Care: Comparative Effectiveness on Retention, Utilization, and Cost. Population health management, 22(4), 292–299. *https://doi.org/10.1089/pop.2018.0163.*

[100] Mohlman MK, Tanzman B, Finison K, Pinette M, Jones C. Impact of Medication-Assisted Treatment for Opioid Addiction on Medicaid Expenditures and Health Services Utilization Rates in Vermont. J Subst Abuse Treat. 2016 Aug; 67:9–14. doi: 10.1016/j.jsat.2016.05.002. Epub 2016 May 9. PMID: 27296656.

retention, fewer hospital stays, and lower costs.

These findings are consistent with a 2016 cross sectional study that evaluated medical claims for Vermont Medicaid beneficiaries with opioid dependence or addiction between 2008 and 2013. In their analysis, Mohlman and colleagues determined that medication combined with psychosocial counseling is associated with reduced general health care expenditures and utilization, such as inpatient hospital admissions and outpatient emergency department visits, for Medicaid beneficiaries with opioid misuse.[100] Two prior studies assessed data from commercial health insurance claims on the overall health care costs and utilization rates for those taking MOUD compared to those treated without MOUD.[101] [102] The first study found that over a five-year period, members on MOUD had 50% lower total annual health plan costs than those who had two or more visits to an addiction treatment setting and no treatment, and 62% lower than those with zero or one visit for addiction treatment and no intervention.[101] The other study found that after a six-month period, those taking MOUD had significantly lower overall annual health plan costs compared to those with no medication ($10,192 vs. $14,353; p-value < 0.0001).[102] The difference was driven largely by lower inpatient services and non-opioid-related outpatient services for the group receiving medication.

The regulatory impact analysis (RIA) outlined below, relies on data provided to SAMHSA by OTP Accreditation Bodies for the year 2020–2021. Pursuant to 42 CFR part 8, Accreditation Bodies and OTPs are required to submit information to SAMHSA's Center for Substance Abuse Treatment (CSAT). The annualized burden of information collection for OTPs and Accreditation Bodies under the rule is set forth in the tables that follow.

This rule does not substantially alter current reporting burden requirements, or accreditation activities. The total number of burden hours reported in 2020–2021 for Accreditation Body respondents was approximately 394.70 hours. The total number of burden hours for OTP respondents during the same period was 1,868.95 hours. The annual burden associated with this rule and the associated forms was estimated to be 2,263.65 hours.

b. Estimated Costs of Reporting Burdens for OTPs and Accreditation Bodies

In developing its estimates of the potential costs of the final regulation, the Department relied substantially on recent estimates of burden and cost pertaining to requirements set forth in 42 CFR part 8.

Hourly labor costs involved in reporting requirements vary greatly between programs. Based on wage estimates obtained from the U.S. Department of Labor, Bureau of Labor Statistics, and Occupational Employment Statistics website, it is estimated that employees involved in complying with reporting requirements range from minimum wage ($7.25) clerical workers, to counselors averaging $22.14 an hour, managers, licensed practical nurses and registered nurses averaging $35.36 per hour, administrators averaging $52.58 per hour, and physicians averaging $96.26 per hour. The estimated average hourly wage for program personnel involved in reporting requirements, calculated as a simple mean, is $42.71. Multiplying the estimated average hourly wage by 2.0 to account for fringe benefits and overhead costs, an estimated hourly labor cost of $85.42 is obtained. The cost to Accreditation Bodies for applying for initial and ongoing approval with Form SMA–163, as well as for complying with the reporting requirements under 42 CFR 8.4 and 8.6 may be estimated at $33,672.56, using the $85.42 hourly cost figure. The estimated total annualized cost to the treatment program respondents for preparing the Form SMA–162 and for complying with other reporting requirements pursuant to 42 CFR 8.11, 8.24, 8.25, 8.26, and 8.28, using $85.42 as the hourly cost figure, is $16,140.11.

Items	Preparation time (hours)	Cost/hour	Total cost
Form SMA–163, compliance with the reporting requirements under 42 CFR 8.4 and 8.6	394.2	$85.42	$33,672.56
Form SMA–162, compliance with other reporting requirements under 21 CFR 8.11, 8.24, 8.25, 8.26, and 8.28	188.95	85.42	16,140.11
Form SMA–168, Exception Request and Record of Justification Under 42 CFR 8.11(h)	2,135	85.42	182,371.70
Sub total	.....	.....	$232,184.37

c. Cost Pertaining to Record Keeping

The record-keeping requirements set forth in 42 CFR 8.4 and 8.12 include maintenance of the following: a patient's medical examination when admitted to treatment; a patient's history; a care plan; any prenatal support provided to the patient; justification of unusually large initial doses; changes in a patient's dosage schedule; the rationale for decreasing a patient's clinic attendance; services provided; and documentation of physiologic tolerance.

SAMHSA believes that the record-keeping requirements are customary and usual practices within the medical and behavioral health treatment communities. Accreditation Bodies also maintain accreditation records for 5 or more years as a customary and usual practice. SAMHSA has neither calculated a response burden or a cost burden for these activities, nor did commenters provide such information.

Costs Pertaining to Disclosure

The final rule includes requirements that OTPs and accreditation organizations disclose information. For example, § 8.12(e)(1) requires that a practitioner explain the facts concerning the use of MOUD to each patient. This type of disclosure is consistent with common medical practice and is not considered an additional burden. Further, the rule requires, under § 8.4(i)(1), that accreditation organizations shall make public their fee structure. This type of disclosure is standard business practice and is not considered a burden in this analysis.

[101] McCarty D, Perrin NA, Green CA, Polen MR, Leo MC, Lynch F (2010). Methadone maintenance and the cost and utilization of health care among individuals dependent on opioids in a commercial health plan. Drug Alcohol Depend. 2010 Oct 1;111(3):235–40. doi: 10.1016/j.drugalcdep.2010.04.018. PMID: 20627427; PMCID: PMC2950212.

[102] Baser O, Chalk M, Fiellin DA, Gastfriend DR. (2011). Cost and utilization outcomes of opioid-dependence treatments. Am J Manag Care. 2011 Jun;17 Suppl 8:S235–48. PMID: 21761950.

e. Estimate of Annualized Non-Hourly Cost Burden to Respondents

The final rule does not impose new capital or startup costs beyond the normal office and laboratory equipment required for achieving regulatory compliance. It is estimated that there are some costs associated with preparation for the accreditation site visit itself; assuming that OTP staff spend approximately 180 hours preparing for the site visit at an average cost of $85.42 per hour and an average of 1.33 site visits per facility, the total cost would be $20,450 or an annualized cost of $15,376 per facility. For the current approximately 2,000 affected OTPs these total annual costs are estimated to be $30,752,000. The percentage of this total cost that is associated with record keeping and reporting-only is difficult to estimate, but it is considered to be a small fraction of the total associated with accreditation.

i. Estimate of Annualized Cost to the Government

The total annualized cost to SAMHSA for administering 42 CFR part 8 is estimated at $450,000. This estimate includes the cost of an outside contractor to develop and maintain an extensive on-line protected website for day-to-day regulatory activities that can be used by SAMSHA, opioid treatment programs, State Opioid Treatment Authorities, Accreditation Bodies and other stakeholders. This estimate does not include funds that SAMHSA/Center for Substance Abuse Treatment (CSAT) allocates to its ''look back'' program that monitors the adequacy of accreditation surveys. Of this amount, the total annualized cost to SAMHSA for Paperwork Reduction Act activities as a result of this regulation is estimated as $221,434, as shown in the following table.

ANNUALIZED COST TO SAMHSA/CSAT

Item (purpose)	Responses	Hours per response	Total hours	Total cost@ $85.42 per hour
SMA–162 (New Programs)	42	1.5	63	$5,381
SMA–162 (Renewal)	386	.75	289.5	24,729
SMA–162 (Relocation)	35	.25	8.75	747
Notification of Provisional Certification	40	.50	20	1,708
Notification of Extension of Provisional Certification	15	.50	7.5	641
Notification of Sponsor or Medical Director Change	60	0.33	19.8	1,691
Documentation to SAMHSA for Interim Treatment	1	0.50	0.5	43
Requests to SAMHSA for Exemption from §§ 8.11 and 8.12 (including SMA–168)	24,000	0.07	1680	143,506
Notification to SAMHSA Before Establishing Medication Units	20	1.00	20	1,708
Review of Submissions under Part C	2	2.00	4	342
Accreditation Body Initial Application (SMA–163)	3	40	120	10,250
Accreditation Body Renewal (SMA–163)	3	40	120	10,250
Relinquishment Notification	1	.50	0.5	43
Notification for Serious Non-Compliant Programs	2	.50	1	85
General Documents to SAMHSA Upon Request	10	1.00	10	854
Accreditation Survey to SAMHSA Upon Request	383	.50	191.5	16,358
Less Than Full Accreditation Report to SAMHSA	10	1.00	10	854
Summaries of Inspections	12	1.00	12	1,025
Notification of Complaints to SAMHSA	10	1.00	10	854
Submission of 90-Day Corrective Plan to SAMHSA	1	4.25	4.25	363
Sub total	25,03625,036	97.15	2592.3	221,434

2. Consideration of Regulatory Alternatives

The Department has completed rulemaking to make flexibilities issued during the COVID–19 PHE permanent, while also updating accreditation and treatment standards to reflect evidence-based practices and current medical terminology and approaches to OUD treatment given the current overdose crisis. The alternative would be to allow the current flexibilities to lapse with the end of the COVID–19 PHE, or to renew them periodically as may be needed during future emergencies or changed circumstances. This is considered to be suboptimal as it creates uncertainty among patients and OTPs, while also constraining access to care. Rulemaking, on the other hand, allows OTPs and their patients to operate in a stable and regulated environment that promotes access to evidence-based interventions. Other changes in the rule impact Accreditation Body oversight and procedures. Such changes can only be effectuated in a regulatory setting.

B. Regulatory Flexibility Act

The Department has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The Act defines ''small entities'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, and (3) a small government jurisdiction of less than 50,000 population. Because 90 percent or more of all health care providers meet the SBA size standard for a small business or are nonprofit organizations, the Department generally treats all health care providers as small entities for purposes of performing a regulatory flexibility analysis. The SBA size standard for health care providers ranges between a maximum of $8 million and $41.5 million in annual receipts, depending upon the type of entity.

Pursuant to the RFA (5 U.S.C. 601–612), the Department asserts a factual basis for its certification that the rule will not have a significant economic impact on a substantial number of small entities. As discussed in the Regulatory

Impact Analysis (RIA) the costs associated with compliance are minimal. As such, the Department certifies that the proposed rule will not impose a significant economic impact. The RIA contains the factual details supporting this certification, affirming the conclusion that the financial impact of compliance is insubstantial in relation to the affected entities' financial operations.

C. Unfunded Mandates Reform Act

Section 202(a) of The Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending that may result in expenditures in any one year of $100 million in 1995 dollars, updated annually for inflation. As of 2023, this threshold is $165 million. The Department does not anticipate that this final rule would result in the expenditure by State, local, and Tribal governments, taken together, or by the private sector, of $165 million or more in any one year.

D. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. The Department does not believe that this rulemaking would have any significant federalism implications, impose significant costs on State or local governments or preempt State law.

E. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 [103] requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Department believes that the final regulations would positively impact the ability of patients and families to access treatment for OUD. The Department does not anticipate negative impacts on family well-being as a result of this rule.

F. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (Pub. L. 104–13), agencies are required to submit to the Office of Management and Budget (OMB) for review and approval any reporting or recordkeeping requirements inherent in a proposed or final rule, and are required to publish such requirements for public comment. The PRA requires agencies to provide a 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;

2. The accuracy of the agency's estimate of the information collection burden;

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.

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department explicitly sought public comment on its assumptions as they relate to the PRA requirements summarized in this section. No applicable comments were received.

As discussed below, the Department estimates a total OTP burden associated with all information collections of 1,868.95 hours, and a total number of burden hours for Accreditation Body respondents of approximately 394.70 hours each year. The annual burden associated with this rule and the associated forms is therefore estimated to be 2,263.65 hours.

1. Explanation of Estimated Annualized Burden Hours for 42 CFR Part 8

The Department presents, in separate tables below, burden estimates for the annual reporting requirement for Accreditation Bodies and OTPs pursuant to the final rule.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.3(b)(1) through (11) ..	Initial approval (SMA–163)	1	1	1	6.0	6
8.3(c)	Renewal of approval (SMA–163)	2	1	2	1.0	2
8.3(e)	Relinquishment notification	1	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs.	1	90	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs.	2	2	4	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance.	2	10	20	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	30	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request.	6	75	450	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request.	6	6	36	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA.	6	5	30	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	300	0.5	150
8.4(e)	Notifications of Complaints	12	6	72	0.5	36

[103] Public Law 105–277, 112 Stat. 2681 (October 21, 1998).

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES—Continued

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs.	1	185	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA.	1	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status.	1	185	185	0.3	55.5
Sub total		54		1,407		394.70

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
8.11(b)	Renewal of approval (SMA–162)	386	1	386	0.15	57.9
8.11(b)	Relocation of Program (SMA–162).	35	1	35	1.17	40.95
8.11(d)	Application for provisional certification.	42	1	42	1	42.00
8.11(f)	Application for extension of provisional certification.	30	1	30	0.25	7.50
8.11(g)(5)	Notification of sponsor or medical director change (SMA–162).	60	1	60	0.1	6.00
8.11(h)(2)	Documentation to SAMHSA for interim treatment.	1	1	1	1	1.00
8.11(i)	Request to SAMHSA for Exemption from §§ 8.11 and 8.12 (including SMA–168).	1,200	20	24,000	0.07	1,680
8.11(j)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA–162).	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Opioid Treatment Authority For Interim Treatment.	1	20	20	0.33	6.6
8.24	Contents of Appellant Request for Review of Suspension.	2	1	2	0.25	.50
8.25(a)	Informal Review Request	2	1	2	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement.	2	1	2	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review.	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement.	2	1	2	5.00	10.00
Sub total		1,775		24,594		1,868.95
Total		1,829		26,001		2,263.65

The tables above reflect current estimates of burden, as the final rule does not effectively add or alter new reporting requirements. The estimates are derived from SAMHSA's data and are reflective of work from over the preceding eighteen months. Further to this, the estimates of burden do not substantially differ from previously submitted estimates provided to The Office of Management and Budget. Recognizing the importance of expanding access to care, the Department has been careful to limit additional burden.

The final rule does not alter reporting requirements as these have been shown to be effective in the safe administration of OTPs. The accreditation system provides effective oversight, while OTP reporting requirements support accreditation activities and the provision of safe treatment. Further to this, the final rule retains requirements that OTP's and accreditation organizations disclose information related to patient care and clinic policies and procedures for the treatment of OUD with MOUD. For example, § 8.12(e)(1) requires that a health care practitioner explain the facts concerning the use of MOUD to each patient. This type of disclosure is considered to be consistent with common medical practice and is not considered an additional burden. Further, the requirement under § 8.4(i)(1) that each accreditation organization shall make public its fee structure is considered standard business practice and is not considered a burden in this analysis.

List of Subjects in 42 CFR Part 8

Administrative practice and procedure, Health professions, Methadone, Reporting and recordkeeping requirements, Substance misuse.

■ For the reasons stated in the preamble, the Department of Health and Human

Services revises 42 CFR part 8 to read as set forth below:

PART 8—MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER

Subpart A—General Provisions

Subpart B—Accreditation of Opioid Treatment Programs

Subpart C—Certification and Treatment Standards for Opioid Treatment Programs

Subpart D—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

Subpart E [Reserved]

Authority: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd–2, 300x–23, 300x–27(a), 300y–11.

Subpart A—General Provisions

§ 8.1 Scope.

(a) *Scope.* This subpart and subparts B through D of this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether an applicant seeking to become an Opioid Treatment Program (OTP) is qualified under section 303(h) of the Controlled Substances Act (CSA) (21 U.S.C. 823(h)) to dispense Medications for Opioid Use Disorder (MOUD) in the treatment of Opioid Use Disorder (OUD), and establishes the Secretary's standards regarding the appropriate quantities of MOUD that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(h)). Under this subpart and subparts B through D, an applicant seeking to become an OTP must first obtain from the Secretary or, by delegation, from the Assistant Secretary for Mental Health and Substance Use, a certification that the applicant is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the applicant obtaining accreditation from an Accreditation Body that has been approved by the Secretary. This subpart and subparts B through D also establish the procedures whereby an entity can apply to become an approved Accreditation Body, and the requirements and general standards for Accreditation Bodies to ensure that OTPs are consistently evaluated for compliance with the Secretary's standards for treatment of OUD with MOUD.

(b) *Severability.* Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be construed so as to give it the maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§thnsp;8.2 Definitions.

The following definitions apply to this part:

Accreditation Body or ''*the Body*'' means an organization that has been approved by the Secretary in this part to accredit OTPs dispensing MOUD.

Accreditation Body application means the application filed with the Secretary for purposes of obtaining approval as an Accreditation Body, as described in § 8.3(b).

Accreditation elements mean the elements or standards that are developed and adopted by an Accreditation Body and approved by the Secretary.

Accreditation survey means an onsite or virtual review and evaluation of an OTP by an Accreditation Body for the purpose of determining compliance with the Federal opioid use disorder treatment standards described in § 8.12.

Accredited OTP means an OTP that is the subject of a current, valid accreditation from an Accreditation Body approved by the Secretary under § 8.3(d).

Behavioral health services means any intervention carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered clinical interventions (*e.g.,* cognitive behavior therapy or insight-oriented psychotherapy) delivered in-person, or remotely via telehealth or telemedicine, which has been shown to facilitate treatment outcomes, or non-clinical interventions.

Care plan means an individualized treatment and/or recovery plan that outlines attainable treatment goals that have been identified and agreed upon between the patient and the OTP clinical team, and which specifies the services to be provided, as well as the proposed frequency and schedule for their provision.

Certification means the process by which the Secretary determines that an OTP is qualified to provide OUD treatment under the Federal Opioid Use Disorder treatment standards.

Certification application means the application filed by an OTP for purposes of obtaining certification from the Secretary, as described in § 8.11(b).

Certified opioid treatment program means an OTP that is the subject of a current, valid certification under § 8.11.

Comprehensive treatment is treatment that includes the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services.

Conditional certification is a type of temporary certification granted to an OTP that has requested renewal of its certification and that has received temporary accreditation for one year by an approved Accreditation Body. The one-year accreditation period is to allow the OTP to address areas of significant non-conformance with accreditation standards that do not involve immediate, high-risk health and/or safety concerns.

Continuous medication treatment means the uninterrupted treatment for OUD involving the dispensing and administration of MOUD at stable dosage levels for a period in excess of 21 days.

Dispense means to deliver a controlled medication to an ultimate user by, or pursuant to, the lawful order

of, a practitioner, including the prescribing and administering of a controlled medication.

Diversion control plan means a set of documented procedures that reduce the possibility that controlled medications will be transferred or otherwise shared with others to whom the medication was not prescribed or dispensed.

Federal Opioid Use Disorder treatment standards means the standards established by the Secretary in § 8.12 that are used to determine whether an OTP is qualified to engage in OUD treatment. The Federal Opioid Use Disorder treatment standards established in § 8.12 also include the standards established by the Secretary regarding the quantities of MOUD which may be provided for unsupervised, take-home use.

For-cause inspection means an inspection, by the Secretary, an Accreditation Body, or a State authority, of an OTP that may be operating in violation of Federal Opioid Use Disorder treatment standards, may be providing substandard treatment, may be serving as a possible source of diverted medications, or where patient well-being is at risk.

Harm reduction refers to practical and legal evidence-based strategies, including: overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services.

Individualized dose means the dose of a medication for opioid use disorder, ordered by an OTP practitioner and dispensed to a patient, that sufficiently suppresses opioid withdrawal symptoms. Individualized doses may also include split doses of a medication for opioid use disorder, where such dosing regimens are indicated.

Interim treatment means that on a temporary basis, a patient may receive some services from an OTP, while awaiting access to more comprehensive treatment services. The duration of interim treatment is limited to 180 days.

Long-term care facilities mean those facilities that provide rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include: extended acute care facilities; rehabilitation centers; skilled nursing facilities; permanent supportive housing; assisted living facilities; and chronic care hospitals.

Medical director means a physician, licensed to practice medicine in the jurisdiction in which the OTP is located, who assumes responsibility for all medical and behavioral health services provided by the program, including their administration. A medical director may delegate specific responsibilities to authorized program physicians, appropriately licensed non-physician practitioners with prescriptive authority functioning under the medical director's supervision, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP, in compliance with applicable Federal and State laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP.

Medication for Opioid Use Disorder or *MOUD* means medications, including opioid agonist medications, approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for use in the treatment of OUD. As used in this part, ''continuous medication treatment'' is intended to be synonymous with the term ''maintenance'' treatment as used in 21 U.S.C. 823(h)(1), and the term ''withdrawal management'' is intended to be synonymous with the term ''detoxification'' as used in 21 U.S.C. 823(h)(1).

Medication unit means an entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a brick-and-mortar location or mobile unit.

Nationally recognized evidence-based guidelines mean a document produced by a national or international medical professional association, public health agency, such as the World Health Organization, or governmental body with the aim of assuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions for the management of OUD and other health conditions that are widely recognized within the United States.

Opioid Treatment Program or *OTP* means a program engaged in OUD treatment of individuals with MOUD registered under 21 U.S.C. 823(h)(1).

Opioid Treatment Program certification means the process by which the Secretary determines that an OTP applicant is qualified to provide Opioid Use Disorder treatment under the Federal Opioid Use Disorder treatment standards described in § 8.12.

Opioid Use Disorder means a cluster of cognitive, behavioral, and physiological symptoms associated with a problematic pattern of opioid use that continues despite clinically significant impairment or distress within a 12-month period.

Opioid Use Disorder treatment means the dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan, to an individual to alleviate the combination of adverse medical, psychological, or physical effects associated with an OUD.

Patient, for purposes of this part, means any individual who receives continuous treatment or withdrawal management in an OTP.

Physical and behavioral health services include services such as medical and psychiatric screening, assessments, evaluations, examinations, and interventions, counseling, health education, peer support services, and social services (*e.g.,* vocational and educational guidance, employment training), that are intended to help patients receiving care in OTPs achieve and sustain remission and recovery.

Practitioner, for purposes of this part, means a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP.

Program sponsor means the person named in the application for certification described in § 8.11(b) as responsible for the operation of the OTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, behavioral health, or social services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall ensure that an actively licensed physician occupies the position of medical director within an OTP.

Recovery support services means:

(1) *Recovery* is the process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential.

(2) *Recovery support services* can include, but are not limited to, community-based recovery housing, peer recovery support services, social support, linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. The services extend the continuum of care by strengthening and complementing substance use disorder (SUD) treatment interventions in different settings and stages.

Split dosing means dispensing of a single dose of MOUD as separate portions to be taken within a 24-hour period. Split dosing is indicated among, but not limited to, those patients who: possess a genetic variant which increases methadone metabolism; concurrently take other medications or drink alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent pain indication in addition to the diagnosis of OUD. This leads to more stable, steady-state medication levels.

State Opioid Treatment Authority (SOTA) is the agency designated by the Governor of a State, or other appropriate official designated by the Governor, to exercise the responsibility and authority within the State or Territory for governing the treatment of OUD with MOUD in OTPs.

Telehealth or *telemedicine, for purposes of this part,* is the delivery and facilitation of health and health-related services including medical care, counseling, practitioner, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies. This includes Health Insurance Portability and Accountability Act (HIPAA)-compliant video and audio-only communication platforms.

Withdrawal management means the dispensing of a MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such period. Long-term withdrawal management refers to the process of medication tapering that exceeds 30 days.

Subpart B—Accreditation of Opioid Treatment Programs

§ 8.3 Application for approval as an Accreditation Body.

(a) *Eligibility.* Private nonprofit organizations, State or territorial governmental entities, or political subdivisions thereof, and Indian Tribes as defined by the Federally Recognized Indian Tribe List Act of 1994, that are capable of meeting the requirements of this part may apply for approval as an Accreditation Body.

(b) *Application for initial approval.* Electronic copies of an Accreditation Body application form [SMA–167] shall be submitted to: *https://dpt2.samhsa.gov/sma163/.* Accreditation Body applications shall include the following information and supporting documentation:

(1) Name, address, and telephone number of the applicant and a responsible official for the Accreditation Body. The application shall be signed by the responsible official;

(2) Evidence of the nonprofit status of the applicant (*i.e.,* of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State or territorial governmental entity, Indian Tribe, or political subdivision;

(3) A set of the accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid use disorder treatment standards set forth in § 8.12;

(4) A detailed description of the applicant's decision-making process, including:

(i) Procedures for initiating and performing onsite accreditation surveys of OTPs;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process, including a request for a complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation is true and accurate, and that no material fact has been omitted;

(iv) Policies and procedures for notifying OTPs and the Secretary of deficiencies, for monitoring corrections of deficiencies by OTPs and for reporting corrections to the Secretary;

(v) Policies and procedures for determining OTPs level of adherence to this part and Accrediting Body standards and level of accreditation;

(vi) Policies and procedures for suspending or revoking an OTP's accreditation;

(vii) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by the Secretary; and

(viii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions;

(5) Policies and procedures established by the Accreditation Body to avoid conflicts of interest, or the appearance of conflicts of interest, by the applicant's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives;

(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician with experience treating OUD with MOUD on the applicant's staff;

(7) A description of the applicant's survey team training policies;

(8) Fee schedules, with supporting cost data;

(9) Satisfactory assurances that the Body will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);

(10) Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an Accreditation Body; and

(11) Any other supporting information the Secretary may require.

(c) *Application for renewal of approval.* An Accreditation Body that intends to continue to serve as an Accreditation Body beyond its current term shall apply to the Secretary for renewal, or notify the Secretary of its intention not to apply for renewal, in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of an Accreditation Body's term of approval, the Body shall inform the Secretary in writing of its intent to seek renewal.

(2) The Secretary will notify the applicant of the relevant information, materials, and supporting documentation required under paragraph (b) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 3 months before the date of expiration of the Accreditation

Body's term of approval, the applicant shall send to the Secretary electronically a renewal application containing the information, materials, and supporting documentation requested by the Secretary under paragraph (c)(2) of this section.

(4) An Accreditation Body that does not intend to renew its approval shall so notify the Secretary at least 9 months before the expiration of the Body's term of approval.

(d) *Rulings on applications for initial approval or renewal of approval.* (1) The Secretary will grant an application for initial approval or an application for renewal of approval if it determines the applicant substantially meets the Accreditation Body requirements of this subpart.

(2) If the Secretary determines that the applicant does not substantially meet the requirements set forth in this subpart, the Secretary will notify the applicant of the deficiencies in the application and request that the applicant resolve such deficiencies within 90 days of receipt of the notice. If the deficiencies are resolved to the satisfaction of the Secretary within the 90-day time period, the Body will be approved as an Accreditation Body. If the deficiencies have not been resolved to the satisfaction of the Secretary within the 90-day time period, the application for approval as an Accreditation Body will be denied.

(3) If the Secretary does not reach a final decision on a renewal application before the expiration of an Accreditation Body's term of approval, the approval will be deemed extended until the Secretary reaches a final decision, unless an Accreditation Body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of approval.* An Accreditation Body that intends to relinquish its accreditation approval before expiration of the Body's term of approval shall submit a letter of such intent to the Secretary, at the address in paragraph (b) of this section, at least 9 months before relinquishing such approval.

(f) *Notification.* An Accreditation Body that does not apply for renewal of approval, or is denied such approval by the Secretary, relinquishes its accreditation approval before expiration of its term of approval, or has its approval withdrawn, shall:

(1) Transfer copies of records and other related information as required by the Secretary to a location, including another Accreditation Body, and according to a schedule approved by the Secretary; and

(2) Notify, in a manner and time period approved by the Secretary, all OTPs accredited or seeking accreditation by the Body that the Body will no longer have approval to provide accreditation services.

(g) *Term of approval.* An Accreditation Body's term of approval is for a period not to exceed 5 years.

(h) *State, territorial, or Indian Tribe Accreditation Bodies.* State, territorial, and Indian Tribe entities, including political subdivisions thereof, may establish organizational units that may act as Accreditation Bodies, provided such units meet the requirements of this section, are approved by the Secretary under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support MOUD.

§ 8.4 Accreditation Body responsibilities.

(a) *Accreditation surveys and for cause inspections.* (1) Accreditation Bodies shall conduct routine accreditation surveys for initial accreditation, and then at least every three years to allow for renewal of certification.

(2) Accreditation Bodies must agree to conduct for-cause inspections upon the request of the Secretary.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved Accreditation Body application.

(b) *Response to noncompliant programs.* (1) If an Accreditation Body receives or discovers information that suggests that an OTP is not meeting applicable accreditation or certification standards established or authorized under this part, or if a survey of the OTP by the Accreditation Body demonstrates that such standards are not being met, the Accreditation Body shall, within 60 days following discovery of the non-compliant condition(s) or applicable survey date:

(i) Provide written notice to the OTP that identifies each area of non-compliance, categorizes each non-compliant condition as either ''minor'' or ''significant'' as determined by the Accrediting Body, and requires the OTP to take corrective action to address the area(s) of non-compliance within a schedule, not to exceed 180 days, that the Accrediting Body deems appropriate based on the severity of the non-compliant conditions; and

(ii) Provide the Secretary with a copy of the written notice required under paragraph (b)(1)(i) of this section.

(2) Once an Accreditation Body provides an OTP with the notice described in paragraph (b)(1)(i) of this section, it shall verify the implementation of the corrective measures by the OTP within the specified schedule. Within 30 days following the last day of the specified schedule, the Accreditation Body shall provide written notice to the Secretary regarding whether the OTP has implemented the corrective measures.

(3) OTPs that are meeting the requirements of § 8.12, but are only required to correct minor non-compliant conditions shall be granted a three-year accreditation, beginning from the end date of the current and expiring accreditation period. Minor non-compliant conditions, found at the time of the survey that are not resolved, as determined by the Accreditation Body, within the OTP's three-year accreditation period and that remain areas of non-compliance during the OTP's subsequent three-year accreditation renewal survey, shall automatically be categorized as ''significant'' non-compliant conditions for purposes of the renewal survey and must be corrected in accordance with paragraph (b)(1)(i) of this section.

(4) OTPs that are required to correct significant non-compliant conditions shall be granted a one-year accreditation, beginning from the end date of the current and expiring accreditation period. An OTP's accreditation must be revoked if it fails to correct significant non-compliant conditions within the schedule provided under paragraph (b)(1)(i) of this section. If an Accrediting Body verifies that an OTP has corrected the significant non-compliant conditions identified within the specified schedule, it shall extend the OTP's accreditation period by an additional two years.

(5) In cases of severe non-compliance with the requirements of § 8.12 that pose immediate risks to patient health and safety, the Accreditation Body shall inform the OTP and Secretary within 48 hours and provide a detailed written report of the non-compliance within 5 business days. The Accreditation Body shall give the OTP 30 days from the date of the non-compliance report to correct the non-compliance issue(s). A follow-up survey shall be conducted by the Accreditation Body within 30 days of the expected correction date to ensure successful remediation. Should the OTP not rectify the non-compliance within the 30-day period, the Accreditation Body shall revoke the OTP's

accreditation. The Secretary will then make a decision regarding the OTP's certification in accordance with the procedures under § 8.13.

(c) *Recordkeeping.* (1) Accreditation Bodies shall maintain, and make available as requested by the Secretary, records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the Accreditation Body.

(2) Accreditation Bodies shall establish procedures to protect confidential information collected or received in their role as Accreditation Bodies that are consistent with, and that are designed to ensure compliance with, all Federal and State laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out Accreditation Body responsibilities shall not be used for any other purpose or disclosed, other than to the Secretary or its duly designated representatives, unless otherwise required by law or with the consent of the OTP.

(ii) Nonpublic information that the Secretary shares with the Accreditation Body concerning an OTP shall not be further disclosed except with the written permission of the Secretary.

(d) *Reporting.* (1) Accreditation Bodies shall provide to the Secretary any documents and information requested by the Secretary within 5 days of receipt of the request.

(2) Accreditation Bodies shall submit a summary of the results of each accreditation survey to the Secretary within 90 days following the survey visit. Such summaries shall contain sufficient detail to justify the accreditation action taken.

(3) Accreditation Bodies shall provide the Secretary a list of each OTP surveyed, and the identity of all individuals involved in the conducting and reporting of survey results.

(4) Accreditation Bodies shall submit to the Secretary the name of each OTP for which the Accreditation Body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to the Secretary under paragraphs (d)(1) through (4) of this section, each Accreditation Body shall submit to the Secretary semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

(6) All reporting requirements listed in this section shall be provided to the Secretary at the address specified in § 8.3(b).

(e) *Complaint response.* Accreditation Bodies shall have policies and procedures in place to respond to complaints received from the Secretary, patients, facility staff, and others within 5 business days from the receipt of the complaint. Accreditation Bodies shall also agree to notify the Secretary within 5 business days of receipt of a complaint from a patient, facility, staff or others, and to inform the Secretary of their response to the complaint.

(f) *Modifications of accreditation elements.* Accreditation Bodies shall obtain the Secretary's written authorization prior to making any substantive (*i.e.,* noneditorial) change in accreditation elements.

(g) *Conflicts of interest.* The Accreditation Body shall maintain and apply policies and procedures that the Secretary has approved in accordance with § 8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the Accreditation Body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision.

(h) *Accreditation teams.* (1) An Accreditation Body survey team shall consist of healthcare professionals with expertise in OUD treatment. The Accreditation Body shall consider factors such as the size of the OTP, the anticipated number of survey non-compliance issues, and the OTP's accreditation history in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of medications subject to control under the Controlled Substances Act (21 U.S.C. 801 *et seq.*);

(ii) Medical issues relating to the dosing and administration of MOUD for the treatment of OUD;

(iii) Psychosocial counseling of individuals receiving OUD treatment; and

(iv) Organizational and administrative issues associated with OTPs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest. Conflict or perceived conflict of interest must be documented by the Accreditation Body and made available to the Secretary.

(i) *Accreditation fees.* Fees charged to OTPs for accreditation shall be reasonable. the Secretary generally will find fees to be reasonable if the fees are limited to recovering costs to the Accreditation Body, including overhead incurred. Accreditation Body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The Accreditation Body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At the Secretary's request, Accreditation Bodies shall provide to the Secretary financial records or other materials, in a manner specified by the Secretary, to assist in assessing the reasonableness of Accreditation Body fees.

§ 8.5 Periodic evaluation of Accreditation Bodies.

The Secretary will periodically evaluate the performance of Accreditation Bodies primarily by inspecting a selected sample of the OTPs accredited by the Accrediting Body, and by evaluating the Accreditation Body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the Accreditation Body are in compliance with applicable standards under this part. The evaluation will include a determination of whether there are major deficiencies in the Accreditation Body's performance that, if not corrected, would warrant withdrawal of the approval of the Accreditation Body under § 8.6.

§ 8.6 Withdrawal of approval of Accreditation Bodies.

If the Secretary determines that an Accreditation Body is not in substantial compliance with this subpart, the Secretary shall take appropriate action as follows:

(a) *Major deficiencies.* If the Secretary determines that the Accreditation Body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, the Secretary shall withdraw approval of that Accreditation Body.

(1) In the event of a major deficiency, the Secretary shall notify the Accreditation Body of the agency's action and the grounds on which the approval was withdrawn.

(2) An Accreditation Body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the Accreditation Body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by the Secretary.

(b) *Minor deficiencies.* If the Secretary determines that the Accreditation Body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, the Secretary will notify the Body that it has 90 days to submit to the Secretary a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. The Secretary may place the Body on probationary status for a period of time determined by the Secretary, or may withdraw approval of the Body if corrective action is not taken.

(1) If the Secretary places an Accreditation Body on probationary status, the Body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the Accreditation Body's probationary status within a time period and in a manner approved by the Secretary.

(2) Probationary status will remain in effect until such time as the Body can demonstrate to the satisfaction of the Secretary that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If the Secretary determines that an Accreditation Body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, the Secretary may withdraw approval of the Accreditation Body. The Accreditation Body shall notify all OTPs that have been accredited, or are seeking accreditation, of the Accreditation Body's loss of the Secretary's approval within a time period and in a manner approved by the Secretary.

(c) *Reapplication.* (1) An Accreditation Body that has had its approval withdrawn may submit a new application for approval if the Body can provide information to the Secretary to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If the Secretary determines that the new application demonstrates that the Body satisfactorily has addressed the causes of its previous unacceptable performance, the Secretary may reinstate approval of the Accreditation Body.

(3) The Secretary may request additional information or establish additional conditions that must be met before the Secretary approves the reapplication.

(4) The Secretary may refuse to accept an application from a former Accreditation Body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) *Hearings.* An opportunity to challenge an adverse action taken regarding withdrawal of approval of an Accreditation Body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in § 8.28 for expedited review of an immediate suspension would not apply to an Accreditation Body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.

Subpart C—Certification and Treatment Standards for Opioid Treatment Programs

§ 8.11 Opioid Treatment Program certification.

(a) *General.* (1) An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(h)(1)) to dispense MOUD in the treatment of OUD. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense MOUD to individuals for treatment of OUD.

(2) To obtain certification from the Secretary, an OTP must meet the Federal Opioid Use Disorder treatment standards in § 8.12, must be the subject of a current, valid accreditation by an Accreditation Body or other entity designated by the Secretary and must comply with any other conditions for certification established by the Secretary.

(3) OTPs are expected to maintain certification with the Secretary and to comply with any other conditions for certification established by the Secretary. Certification shall be granted for a term not to exceed 3 years, except that certification may be renewed during the final certification year if the OTP applies for certification renewal in accordance with the steps outlined in paragraph (a)(4) of this section.

(4) OTPs which satisfy the criteria for certification under this section may apply for renewal of their certification. OTPs are expected to apply for certification renewal during the final year of the OTP's certification period. OTPs should take steps to ensure that administrative tasks associated with renewal are completed before the OTP's certification expires. OTPs may apply for certification renewal in accordance with the procedures as outlined in paragraph (b) of this section. If an OTP anticipates any delays in routine certification renewal, an extension may be requested by submitting to the Secretary a statement justifying the extension in accordance with paragraph (e) of this section.

(5) OTPs that are certified and are seeking certification renewal, and who have been granted accreditation for one year by an Accreditation Body as provided under § 8.4(b)(1)(iii), may receive a conditional certification for one year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year certification, as described in paragraph (a)(3) of this section, within the 1-year conditional certification period. If standard accreditation is not obtained by the OTP within the 1-year conditional certification period, the OTP's conditional certification will lapse, and the Attorney General will be notified that the OTP's registration should be revoked.

(6) OTPs whose certification has expired, and who seek re-certification, will be considered ''new'' programs and will be required to apply for provisional certification in accordance with paragraph (d) of this section.

(b) *Application for initial or renewal certifications and re-certification.* Applications for certification must be submitted by the OTP using form SMA–162. The application for initial or renewal of certification shall include, as determined by the Secretary:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the of the OTP;

(5) The sources of funding for the OTP and the name and address of each

governmental entity that provides such funding;

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (g) of this section; and

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(8) Applications for re-certification shall include an explanation of why the OTP's most recent certification expired and information regarding the schedule for an accreditation survey.

(c) *Action on application.* (1) Following the Secretary's receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, the Secretary may grant the application for certification, or renew an existing certification, if the Secretary determines that the OTP has satisfied the requirements for certification or renewal of certification in this section.

(2) The Secretary may deny the application if the Secretary determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the Federal Opioid Use Disorder treatment standards established under § 8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification in this section, the Secretary will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide OUD treatment under section 303(g)(1) of the Controlled Substances Act.

(d) *Provisional certification.* New OTPs that have not received the Secretary's certification previously, except as provided in paragraph (a)(6) of this section, who are applying for certification from the Secretary, and who have applied for accreditation with an Accreditation Body, are eligible to receive provisional certification for up to 1 year. To receive provisional certification, an OTP shall submit the information required by paragraph (b) of this section to the Secretary along with a statement identifying the Accreditation Body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph (d), unless the Secretary determines that patient health would be adversely affected by the granting of provisional certification.

(e) *Requirements for certification.* (1) OTPs shall comply with all pertinent Federal and State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of MOUD in the treatment of OUD. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of the Department of Health and Human Services (HHS) or Substance Abuse and Mental Health Services Administration (SAMHSA), by Accreditation Bodies, by the Drug Enforcement Administration (DEA), and by authorized employees of any other Federal governmental entity with legal authority to conduct inspections or surveys on an OTP's premises.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164, and every program must comply with these regulations, as applicable. Records on the receipt, storage, and distribution of MOUD are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*). Federally sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) An OTP or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Department of Health and Human Services or SAMHSA to have access to and to copy all records on the use of MOUD in accordance with the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164.

(5) OTPs shall notify the Secretary in writing within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II and must be registered by the DEA before administering or dispensing MOUD.

(7) OTPs must operate in accordance with Federal Opioid Use Disorder treatment standards and approved accreditation elements.

(f) *Conditions for interim treatment program approval.* (1) Before an OTP may provide interim treatment, the OTP must receive the approval of both the Secretary and the SOTA of the State in which the OTP operates.

(2) Before the Secretary may grant such approval, the OTP must provide the Secretary with documentation from the SOTA of the State in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim treatment in the State;

(ii) The OTP seeking to provide such treatment is unable to provide access for patients in a comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek treatment for OUD;

(iii) The authorization of the OTP to provide interim treatment will not otherwise reduce the capacity of comprehensive treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and

(iv) OTPs providing interim treatment will arrange for each individual's transfer to a comprehensive treatment program no later than 180 days from the date on which each individual first requested treatment. Individuals enrolled in interim treatment shall not be discharged without the approval of an OTP practitioner, who shall consider on-going and patient-centered treatment needs, which are to be documented in the patient record, while awaiting transfer to a comprehensive treatment program.

(3) The Secretary will provide notice to the OTP denying or approving the request to provide interim treatment. The OTP shall not provide such treatment until it has received such notice from the Secretary.

(g) *Exemptions.* An OTP may, at the time of application for certification or any time thereafter, request from the Secretary exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who

wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no OUD treatment services geographically accessible, and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. The Secretary will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. The Secretary shall consult with the appropriate State authority prior to taking action on an exemption request.

(h) *Medication units, long-term care facilities and hospitals.* (1) Certified OTPs may establish medication units that are authorized to dispense MOUD. Before establishing a medication unit, a certified OTP must notify the Secretary by submitting form SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent State laws and regulations. Medication units include both mobile and brick and mortar facilities.

(2) Specifically, any services that are provided in an OTP may be provided in the medication unit, assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space.

(3) Certification as an OTP under this part is not required for the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a hospital, long-term care facility, or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic, for the treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law.

(i) The term ''long-term care facility'' is defined in § 8.2. Nothing in this section is intended to relieve hospitals, or long-term care facilities and correctional facilities that are registered with the Drug Enforcement Administration as a hospital/clinic, from their obligations to obtain appropriate registration from the Attorney General, under section 303(g) of the Controlled Substances Act. Treatment provided under this section should always comply with applicable Federal laws.

(ii) [Reserved]

§ 8.12 Federal Opioid Use Disorder treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* (1) An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part.

(2) The medical director shall assume responsibility for all medical and behavioral health services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current ''Diversion Control Plan'' or ''DCP'' as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of dispensed MOUD, and that assigns specific responsibility to the OTP providers and administrative staff for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials.* Each person engaged in the treatment of OUD must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All practitioners and other licensed/certified health care providers, including counselors, must comply with the credentialing and maintenance of licensure and/or certification requirements of their respective professions.

(e) *Patient admission criteria*—(1) *Comprehensive treatment.* An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: The person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. Such decisions must be appropriately documented in the patient's clinical record. In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD and that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

(2) *Comprehensive treatment for persons under age 18.* Except in States where State law grants persons under 18 years of age the ability to consent to OTP treatment without the consent of another, no person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) *Withdrawal management.* An OTP shall maintain current procedures that are designed to ensure that those patients who choose to taper from MOUD are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks. Such consent must be documented in the clinical record by the treating practitioner.

(f) *Required services*—(1) *General.* OTPs shall provide adequate medical, counseling, vocational, educational, and other screening, assessment, and treatment services to meet patient needs, with the combination and frequency of services tailored to each individual patient based on an individualized assessment and the patient's care plan that was created after shared decision making between the patient and the clinical team. These services must be available at the primary facility, except where the program sponsor has entered into a documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) *Initial medical examination.* (i) OTPs shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts:

(A) A screening examination to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD; and

(B) A full history and examination, to determine the patient's broader health status, with lab testing as determined to be required by an appropriately licensed

practitioner. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

(ii) Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.

(iii) A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full exam can be completed by a non-OTP practitioner, if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

(iv) Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than 30 days prior to admission to the OTP, may form part of the full history and examination.

(v) The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth. When using telehealth, the following caveats apply:

(A) In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(B) In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(3) *Special services for pregnant patients.* OTPs must maintain current policies and procedures that reflect the special needs and priority for treatment admission of patients with OUD who are pregnant. Pregnancy should be confirmed. Evidence-based treatment protocols for the pregnant patient, such as split dosing regimens, may be instituted after assessment by an OTP practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocol. Prenatal care and other sex-specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners. Specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners.

(4) *Initial and periodic physical and behavioral health assessment services.* (i) Each patient admitted to an OTP shall be given a physical and behavioral health assessment, which includes but is not limited to screening for imminent risk of harm to self or others, within 14 calendar days following admission, and periodically by appropriately licensed/credentialed personnel. These assessments must address the need for and/or response to treatment, adjust treatment interventions, including MOUD, as necessary, and provide a patient-centered plan of care. The full, initial psychosocial assessment must be completed within 14 calendar days of admission and include preparation of a care plan that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue. The care plan also must identify the recommended frequency with which services are to be provided. The plan must be reviewed and updated to reflect responses to treatment and recovery support services, and adjustments made that reflect changes in the context of the person's life, their current needs for and interests in medical, psychiatric, social, and psychological services, and current needs for and interests in education, vocational training, and employment services.

(ii) The periodic physical examination should occur not less than one time each year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record.

(5) *Counseling and psychoeducational services.* (i) OTPs must provide adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary and mutually agreed-upon, including harm reduction education and recovery-oriented counseling. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, and engage with patients, to contribute to the appropriate care plan for the patient and to monitor and update patient progress. Patient refusal of counseling shall not preclude them from receiving MOUD.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment each patient admitted or readmitted to treatment who has received positive test results for these conditions from initial and/or periodic medical examinations.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed-upon as beneficial by the patient and program staff.

(6) *Drug testing services.* When conducting random drug testing, OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is

in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient, allowing for extenuating circumstances at the individual patient level. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

(g) *Recordkeeping and patient confidentiality.* (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to MOUD approved for use in treatment of OUD. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to determine whether the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in circumstances involving an inability to access care at the patient's OTP of record. Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure. If the medical director or program practitioner of the OTP in which the patient is enrolled determines that such circumstances exist, the patient may seek treatment at another OTP, provided the justification for the particular circumstances are noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the MOUD.

(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner and if consistent with Federal and State law.

(2) OTPs shall use only those MOUD that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of OUD. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of OUD. Currently the following MOUD will be considered to be approved by the Food and Drug Administration for use in the treatment of OUD:

(i) Methadone;

(ii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of OUD; and

(iii) Naltrexone.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral misuse.

(ii) For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

(4) OTPs shall maintain current procedures adequate to ensure that each MOUD used by the program is administered and dispensed in accordance with its FDA approved product labeling. The program must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) *Unsupervised or ''take-home'' medication doses.* Unsupervised or ''take-home'' medication doses may be provided under the following circumstances:

(1) Any patient in comprehensive treatment may receive their individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (*e.g.,* Sunday) and State and Federal holidays, no matter their length of time in treatment.

(2) OTP decisions on dispensing MOUD to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section shall be determined by an appropriately licensed OTP medical practitioner or the medical director. In determining which patients may receive unsupervised medication doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;

(ii) Regularity of attendance for supervised medication administration;

(iii) Absence of serious behavioral problems that endanger the patient, the public or others;

(iv) Absence of known recent diversion activity;

(v) Whether take-home medication can be safely transported and stored; and

(vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is safely able to manage unsupervised doses of MOUD, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(ii) of this section.

(i) During the first 14 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 7 days, but decisions must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(ii) From 15 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(iii) From 31 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(4) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Pub. L. 91–601 (15 U.S.C. 1471 *et seq.*)). Programs must provide education to each patient on: Safely transporting medication from the OTP to their place of residence; and the safe storage of take-home doses at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

(j) *Interim treatment.* (1) The program sponsor of an OTP may admit an individual, who is eligible for admission to comprehensive treatment, into interim treatment if comprehensive services are not readily available within a reasonable geographic area and within 14 days of the individual's seeking treatment. At least two drug tests shall be obtained from patients during the maximum of 180 days permitted for interim treatment. A program shall establish and follow reasonable criteria for establishing priorities for moving patients from interim to comprehensive treatment. These transition criteria shall be in writing and shall include, at a minimum, prioritization of pregnant patients in admitting patients to interim treatment and from interim to comprehensive treatment. Interim treatment shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the SOTA when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of transfer to comprehensive services, and shall document such notifications.

(3) The Secretary may revoke the interim authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, the Secretary will consider revoking the interim authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(h).

(4) All requirements for comprehensive treatment apply to interim treatment with the following exceptions:

(i) A primary counselor is not required to be assigned to the patient, but crisis services, including shelter support, should be available;

(ii) Interim treatment cannot be provided for longer than 180 days in any 12-month period;

(iii) By day 120, a plan for continuing treatment beyond 180 days must be created, and documented in the patient's clinical record; and

(iv) Formal counseling, vocational training, employment, economic, legal, educational, and other recovery support services described in paragraphs (f)(4) and (f)(5)(i) and (iii) of this section are not required to be offered to the patient. However, information pertaining to locally available, community-based resources for ancillary services should be made available to individual patients in interim treatment.

§ 8.13 Revocation of accreditation and Accreditation Body approval.

(a) *The Secretary's action following revocation of accreditation.* If an Accreditation Body revokes an OTP's accreditation, the Secretary may conduct an investigation into the reasons for the revocation. Following such investigation, the Secretary may determine that the OTP's certification should no longer be in effect, at which time the Secretary will initiate procedures to revoke the program's certification in accordance with § 8.14. Alternatively, the Secretary may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation Body approval.* (1) If the Secretary withdraws the approval of an Accreditation Body under § 8.6, the certifications of OTPs accredited by such Body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the Accreditation Body, unless the Secretary determines that to protect public health or safety, or because the Accreditation Body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. The Secretary may extend the time in which a certification remains in effect under this paragraph (b)(1) on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an Accreditation Body, or within any shorter period of time established by the Secretary, OTPs currently accredited by the Accreditation Body must obtain accreditation from another Accreditation Body. The Secretary may extend the time period for obtaining reaccreditation on a case-by-case basis.

§ 8.14 Suspension or revocation of certification.

(a) *Revocation.* Except as provided in paragraph (b) of this section, the Secretary may revoke the certification of an OTP if the Secretary finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with this subpart, that the program sponsor, or any employee of the OTP:

(1) Has been found to have engaged in misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal Opioid Use Disorder treatment standards in any respect;

(3) Has failed to comply with reasonable requests from the Secretary or from an Accreditation Body for records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal Opioid Use Disorder treatment standards; or

(4) Has refused a reasonable request of a duly designated inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or Accreditation Body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, the Secretary may immediately suspend the certification of an OTP, and notify the Attorney General that the OTP's registration should be suspended, before holding a hearing under this subpart. The Secretary may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under this subpart if the Secretary makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal Opioid Use Disorder treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal Opioid Use Disorder treatment standards was intentional or was associated with fraud.

(c) *Written notification.* In the event that the Secretary suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, the Secretary shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action, state that the OTP may seek review of the action in accordance with the procedures in this subpart, and identify the reviewing official to whom a written request for review may be submitted.

(d) *Procedure.* (1) If the Secretary suspends certification in accordance with paragraph (b) of this section:

(i) The Secretary will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) the Secretary will provide an opportunity for a hearing under this subpart.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

§ 8.15 Forms.

(a) SMA–162—Application for Certification to Use Medications for Opioid Use Disorder.

(b) SMA–163—Application for Becoming an Accreditation Body under § 8.3.

Subpart D—Procedures for Informal Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

§ 8.21 Applicability.

The procedures in this subpart apply when:

(a) The Secretary has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that the Secretary proposes to revoke the certification; and

(b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing to the reviewing official, an opportunity for an informal review of the suspension or proposed revocation.

(c) The Secretary has notified an Accreditation Body of an adverse action taken regarding withdrawal of approval of the Accreditation Body under the regulations in subpart A of this part; and

(d) The Accreditation Body has, within 30 days of the date of the notification, requested in writing an opportunity for a review of the adverse action.

§ 8.22 Definitions.

The following definitions apply to this subpart:

Appellant means:

(1) The OTP which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation; or

(2) The Accreditation Body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.

Respondent means SAMHSA.

Reviewing official means the person or persons designated by the Secretary who will informally review the suspension or proposed revocation. The reviewing official may be assisted by one or more Department of Health and Human Services (HHS) officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

§ 8.23 Limitation on issues subject to review.

The scope of this informal review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts, the regulations in this subpart, and other relevant law.

§ 8.24 Specifying who represents the parties.

The appellant's request for an informal review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

§ 8.25 Informal review and the reviewing official's response.

(a) *Request for review.* Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension, proposed revocation, or adverse action, a brief statement of why the decision to suspend, propose revocation, or take an adverse action is incorrect, and the appellant's request for an oral presentation, if desired.

(b) *Acknowledgment.* Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

§ 8.26 Preparation of the review file and written arguments.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's documents and brief.* Within 30 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's

argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification or to take adverse action regarding withdrawal of approval of the Accreditation Body is incorrect (appellant's brief).

(b) *Respondent's documents and brief.* Within 30 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification, or approval as an Accreditation Body, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension, proposed revocation, or adverse action (respondent's brief).

(c) *Reply briefs.* Within 10 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive documentation.* The reviewing official may take any appropriate steps to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

(f) *Discovery.* The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

§ 8.27 Opportunity for oral presentation.

(a) *Electing oral presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding official.* The reviewing official or designee will be the presiding official responsible for managing the oral presentations.

(c) *Preliminary conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference.

(d) *Time and place of oral presentation.* The presiding official will attempt to schedule the oral presentation within 45 days of the date appellant's request for review is received or within 15 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the oral presentation*—(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more HHS officers or employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of proof/standard of proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend, propose revocation, or take adverse action is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) *Admission of evidence.* The rules of evidence do not apply, and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the pre-hearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of justice or making of false statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1001 or 1505.

(g) *Post-hearing procedures.* At the presiding official's discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

§ 8.28 Expedited procedures for review of immediate suspension.

(a) *Applicability.* When the Secretary notifies an OTP in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 10 days of the date the OTP received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing official's response.* As soon as practicable after the request for review is received, the reviewing official

will send an acknowledgment with a copy to the respondent.

(c) *Review file and briefs.* Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with § 8.27(a), the presiding official will attempt to schedule the oral presentation within 20 to 30 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with § 8.27(c) and will conduct the oral presentation in accordance with the procedures of § 8.27(e), (f), and (g).

(e) *Written decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in § 8.33 apply.

(f) *Transmission of written communications.* Because of the importance of timeliness for the expedited procedures in this section, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.

§ 8.29 Ex parte communications.

For the purposes of maintaining the equity of informal review proceedings, except for routine administrative and procedural matters or as described in §§ 8.22(2) and 8.27(e), a party shall not communicate with the reviewing or presiding official without notice to the other party.

§ 8.30 Transmission of written communications by reviewing official and calculation of deadlines.

(a) *Timely review.* Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, or commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) *Due date.* In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

§ 8.31 Authority and responsibilities of the reviewing official.

In addition to any other authority specified in this subpart, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify the procedures in this subpart in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of the procedures in this subpart.

§ 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

§ 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. The Secretary will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**. The Secretary will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

Subpart E [Reserved]

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–01693 Filed 1–31–24; 4:15 pm]

BILLING CODE 4162–20–P

FEDERAL REGISTER

Vol. 89 Friday,

No. 23 February 2, 2024

Part V

Federal Trade Commission

16 CFR Part 305

Energy Labeling Rule; Proposed Rule

FEDERAL TRADE COMMISSION

16 CFR Part 305

[3084–AB15]

Energy Labeling Rule

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') proposes amendments to improve the Energy Labeling Rule (''Rule''), including energy labels for several new consumer product categories and changes to label display requirements. Specifically, the Notice seeks comment on labels for air cleaners, clothes dryers, miscellaneous refrigeration products, and portable electric spas; modifications to existing labels for clothes washers, televisions, and several heating products; revisions to the current requirements for affixing labels on showroom models; and several minor amendments to improve the Rule as discussed below.

DATES: Comments must be received by April 2, 2024.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Energy Labeling Rule Improvements (16 CFR part 305) (Matter No. R611004)'' on your comment, and file your comment online at *https://www.regulations.gov/,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H–144 (Annex L), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome (202–326–2889), or Hong Park (202–326–2158), Attorneys, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Overview

The Commission seeks comment on several proposed changes to the Energy Labeling Rule including: (1) labels for air cleaners, clothes dryers, miscellaneous refrigeration products, and portable electric spas; (2) modifications to existing labels for clothes washers, televisions, and several heating products; (3) revisions to the current requirements for affixing labels on showroom models; and (4) several minor amendments to improve the Rule as discussed below.

II. Background

The Commission issued the Energy Labeling Rule in 1979,[1] pursuant to the Energy Policy and Conservation Act of 1975 (''EPCA'').[2] The Rule [3] requires energy labeling for major home appliances and other consumer products to help consumers compare competing models. Specifically, it contains labeling requirements for refrigerators, refrigerator-freezers, freezers, dishwashers, water heaters, clothes washers, room and portable air conditioners, furnaces, central air conditioners, heat pumps, plumbing products, lighting products, ceiling fans, and televisions. Under EPCA, the FTC has broad authority to ''require that each covered product in the type or class of covered products to which the rule applies bear a label'' disclosing energy use information. 42 U.S.C. 6294(c)(1). In addition to products named in the statute or designated by DOE, FTC may require labels for any consumer product provided the label ''is likely to assist consumers in making purchasing decisions.'' [4] To achieve this goal, the FTC has discretion to determine both the manner in which the label is displayed as well as the energy-related content of the label.[5] Additionally, the statute gives FTC authority to require retailers to provide labels and other disclosures for consumers, both on websites and in stores.[6]

The Rule requires manufacturers to attach yellow EnergyGuide labels to many covered products and prohibits retailers from removing these labels or rendering them illegible. In addition, it directs sellers, including retailers, to post label information on websites and in paper catalogs from which consumers can order products. EnergyGuide labels for most covered products contain three key disclosures: (1) estimated annual energy cost, (2) a product's energy consumption or energy efficiency rating as determined by DOE test procedures, (3) and a comparability range displaying the highest and lowest energy costs or efficiency ratings for all similar models. For cost calculations, the Rule specifies national average costs for applicable energy sources (*e.g.,* electricity, natural gas, oil) based on DOE estimates. The Rule sets a 2027 date, based on a five-year schedule, for updating comparability range and annual energy cost information based on manufacturer data submitted pursuant to the Rule's reporting requirements.[7]

III. Advance Notice of Proposed Rulemaking

In 2022, the Commission published an Advance Notice of Proposed Rulemaking (''ANPR'') seeking comment on potential improvements to the Energy Labeling Rule, including whether the Commission should add new consumer product categories to the labeling program, change label location to match consumer shopping patterns, and streamline existing requirements.[8] In addition, the ANPR sought comment on several specific issues including whether the Commission should amend the Rule to: (1) modify label content and format, (2) require links to online Lighting Facts labels consistent with current EnergyGuide requirements, (3) update the electricity cost figure on the Lighting Facts and ceiling fan labels, (4) update the refrigerator and clothes washer labels to remove dated information about test procedures, and (5) ensure the Rule's consistency with DOE requirements. Finally, the ANPR sought comment on potential requirements related to repair

[1] 44 FR 66466 (Nov. 19, 1979).

[2] 42 U.S.C. 6294. EPCA also requires the Department of Energy (''DOE'') to develop test procedures that measure how much energy appliances use, and to determine the representative average cost a consumer pays for different types of energy. *See* 10 CFR parts 429 and 430.

[3] 16 CFR part 305.

[4] 42 U.S.C. 6294(a)(6); *see* 42 U.S.C. 6291(1) (defining ''consumer product''). For additional FTC labeling authority, see 42 U.S.C. 6294(a)(1)–(5). For new product categories that DOE classifies as ''covered'' pursuant to 42 U.S.C. 6292(b), the FTC may prescribe labeling under 42 U.S.C. 6294(a)(3) if (1) the Commission determines labeling will assist purchasers in making purchasing decisions, (2) DOE has prescribed test procedures for the product class, and (3) the Commission concludes labeling for the class is economically and technologically feasible.

[5] 42 U.S.C. 6294(c).

[6] EPCA authorizes the Commission to prescribe labeling rules under this section applicable to all covered products, including rules governing label disclosures at the point of sale. *See* 42 U.S.C. 6294(c)(3) and (c)(4) (''A rule under this section applicable to a covered product may require disclosure, in any printed matter displayed or distributed at the point of sale of such product, of any information which may be required under this section to be disclosed on the label of such product.''); *see also* 42 U.S.C. 6298 (authorizing the Commission to issue rules it ''deems necessary to carry out'' the law's provisions). Since its initial promulgation in 1979 (44 FR 66466 (Nov. 19, 1979)), the Rule has contained obligations for retailers to display labels to customers for particular product categories. *See, e.g.,* 16 CFR 305.22(b)(2) (requiring retailers to show consumers the labels for covered central air conditioners, heat pumps, or furnaces prior to purchase); 16 CFR 305.26 (requiring retailers to make written disclosures at the point of sale). In 2014, the Commission sought comment on whether it should require retailers to affix labels on units they display in their appliance showrooms. 79 FR 34642, 34658 (June 18, 2014).

[7] 16 CFR 305.12.

[8] 87 FR 64399 (Oct. 25, 2022).

instructions.[9] The Commission is not seeking further comment on those repair issues at this time. While the Commission is not seeking additional comment at this time, we remain interested and engaged with stakeholders on this issue. As expressed in the *Nixing the Fix* report, we remain concerned about the repairability of products. We continue to review comments, research, legislative initiatives and industry practices as we evaluate next steps.

In response, the Commission received 48 comments, covering the following four areas: (1) potential new product categories; (2) existing product categories; (3) label placement requirements; and (4) miscellaneous issues. The following section summarizes these comments and provides the Commission's analysis.[10]

IV. Labeling for New Product Categories

The ANPR invited comments on whether to add several new product categories to the energy labeling program. In response, commenters provided a range of opinions and information. As discussed below, two expressed support for expanding labeling to all the proposed products, while others focused on specific products. For each specific product, we provide relevant background information, summarize the comments, and analyze the record.

A. Support for Labeling All New Products

Two commenters supported labeling on all new products for which the Commission sought comments in the ANPR but did not discuss individual product categories in detail.[11] Specifically, Earthjustice asserted all these products ''use a substantial amount of energy and exhibit a range of annual energy costs across competing similar models.'' Additionally, the New York State Energy Research and Development Authority (''NYSERDA'') ''strongly support[ed] FTC expanding labeling'' across all the new product categories identified. It noted the importance of consumer energy labeling for the State of New York to meet the State's climate mandates. The NYSERDA further explained that labeling encourages energy-efficiency technology by providing consumers with information to choose efficient products and by encouraging manufacturers to develop higher-efficiency models. It noted that energy efficiency benefits not only homeowners but tenants who pay utility bills but do not choose installed equipment.

B. Air Cleaners (''Air Purifiers'')

Background: Air cleaners (or ''air purifiers'') use significant amounts of energy and exhibit a substantial range of energy use and annual energy costs among similar models. For example, as discussed in the ANPR, recent ENERGY STAR data shows models rated for room sizes between 150 and 299 square feet range in annual energy use from about 50 kWh/yr to 360 kWh/yr, resulting in an estimated annual difference of more than $30 per year in energy costs (assuming $0.14/kWh),[12] a range similar to many refrigerators subject to labeling. Additionally, DOE recently completed proceedings that establish test procedures[13] and final conservation standards[14] for these products.

Comments: As discussed below, commenters addressing air cleaners generally supported energy label requirements once DOE resolved questions regarding its test procedure—which it has done.

While all commenters addressing this issue supported a label, some urged the Commission to set a compliance date that takes into account DOE's rulemaking. For instance, the Joint Commenters, a collection of industry and energy-efficiency organizations, along with the California Investor Owned Utilities (''IOUs''), recommended a December 31, 2025 label compliance date (or three years after final DOE action, whichever is later) to coincide with their recommended compliance date for the second tier of DOE standards and test procedures.[15] The Air-Conditioning, Heating, and Refrigeration Institute (''AHRI'') also recommended FTC wait until DOE publishes a final energy conservation standard before conducting a labeling rulemaking, and then require labeling by the Joint Commenter's recommended compliance date, or no sooner than 2025. In addition, P.R. China, which urged the FTC to refrain from issuing labeling rules until DOE clarifies its test procedure, noted inconsistencies between DOE's proposed test for measuring the Integrated Energy Factor[16] (''IEF'') and the annual energy use (kWh/year) in the ENERGY STAR certification. P.R. China also observed consumers can ''easily check the annual energy usage (kWh/year) of different manufacturers and air purifiers models on the ENERGY STAR website.''[17]

Commenters additionally urged the FTC to include a room size estimate on the label using a single, consistent test method. For instance, the California IOUs explained the lack of a consistent room size metric has led to multiple, inconsistent representations affecting consumers' ability to make informed decisions, even among top-rated products. These utilities also recommended the label disclose the parameters used to calculate recommended room size (*e.g.,* ceiling height, air changes per hour, and air change frequency). The Joint Commenters, which also supported a room size disclosure, urged FTC to communicate a model's recommended room size to consumers using a specific test method (ANSI/AHAM AC–1–2020). Under the recommended procedure, manufacturers would calculate room size in square feet based on the removal of at least 80 percent of smoke particles

[9] Under EPCA the Commission has authority to require manufacturers to provide consumers with ''additional information relating to energy consumption, including instructions for the maintenance, use, or repair of the covered product'' if the Commission finds such information would assist with purchase decisions or in the use of the product, and would not be unduly burdensome to manufacturers. 42 U.S.C. 6294(c)(5).

[10] The comments are available at *www.regulations.gov.*

[11] A third commenter, Merriam, suggested the FTC also consider labeling for electric vehicles. However, the Commission cannot require labels for such products because EPCA specifically excludes automobiles from its definition of consumer products. *See* 42 U.S.C. 6291(1). In addition, the FTC already addresses alternative fuels and alternative fuel vehicles in its Alternative Fuels Rule (16 CFR part 309) and Fuel Economy Guides (16 CFR part 259).

[12] *See, e.g., https://www.energystar.gov/productfinder/product/certified-room-air-cleaners/results.* EPCA does not include air cleaners in its list of covered products, 42 U.S.C. 6292, but the Commission has authority under 42 U.S.C. 6294(a)(3) to require labeling if DOE designates them as ''covered products'' and the Commission finds labeling will assist purchasers in making purchasing decisions and economically and technologically feasible. Additionally, the Commission has independent authority to require labels for room air cleaners pursuant to its general labeling authority under 42 U.S.C. 6294(a)(6) if it determines that labeling ''is likely to assist consumers in making purchasing decisions.''

[13] 88 FR 14014 (Mar. 6, 2023).

[14] 88 FR 21752 (Apr. 11, 2023).

[15] In response to DOE's reopening for comment its Request for Information relating to air cleaner, *see* 87 FR 11326 (Mar. 1, 2022), the Joint Commenters submitted a negotiated joint proposal separating implementation of the relevant standards and test conditions into two tiers and setting December 31, 2023, and December 31, 2025, as the respective compliance deadlines. In the event DOE rejects their proposal, the Joint Commenters requested the FTC set a compliance date that aligns with DOE's compliance date.

[16] The Integrated Energy Factor measures the energy efficiency of air cleaners. It is expressed in the smoke Clean Air Delivery Rate (''CADR'') per watts and accounts for the energy used in both standby mode and operation. *See* 10 CFR Pt. 430, Subpt. B, App. FF at Sec. 7; 88 FR 14014, 14023 (Mar. 6, 2023).

[17] P.R. China, however, recommended that the FTC not require labeling for products without clear test procedures.

in a steady-state room environment (assuming the room experiences incoming pollutants at the rate of one air change per hour) and with complete mixing in the room. The Joint Commenters also urged the use of the CADR value from the AHAM test method to determine the recommended room size, as opposed to an alternative such as ''PM 2.5.'' They explained engineering tobacco smoke used in the test is a surrogate for many of the fine particles found in a home, and thus generates a useful performance metric even for consumers who do not smoke.[18]

Several commenters also urged the Commission to include a CADR disclosure on the label. CADR measures the number of cleaned air exchanges for a given square footage of space and thus describes more than the system's filter efficiency or fan strength. For example, Blueair recommended this disclosure because it is widely accepted within the industry and can highlight ''energy efficiency and power consumption, while also providing information about air filtration.'' According to Blueair, models with a high CADR rating optimize both the filtration efficiency of the air purifier and its airflow to clean the air quickly and effectively from pollutants. Blueair further explained many products on the market offer a high filtration percentage (*i.e.,* ''a single pass filtration efficiency''), but only produce a small volume of clean air and thus are slow to cycle through a room's air.

Blueair, however, opposed including energy costs on labels unless ''accuracy could be assured.'' It explained the test conditions behind such an estimate may involve unrealistic conditions (*e.g.,* ''running products at their highest levels for a period of time'') and may produce ''elevated cost estimates'' inconsistent with actual operation.

Finally, one commenter addressed the label's location and content. Specifically, the Association of Home Appliance Manufacturers (''AHAM'') recommended the Commission require manufacturers to display a new air cleaner label on boxes via a QR code and provided a sample label containing disclosures for annual energy cost, room size, and Integrated Energy Factor.[19]

Discussion: The Commission proposes requiring EnergyGuide labeling for air cleaners. Recent DOE analysis demonstrates significant variability in the energy use of various air cleaner models.[20] Therefore, as discussed above, labeling should assist consumers in their purchasing decisions by allowing them to choose among competing models with a range of energy costs. In addition, such labeling does not appear to raise unique or difficult implementation issues compared to other products already labeled under the Rule, and, therefore, should be economically and technologically feasible.

The proposed amendments require manufactures to affix an EnergyGuide label on air cleaner packages because retailers typically display these products in boxes. The proposed label displays yearly energy costs as the primary disclosure. The label also includes secondary disclosures, which the Commission has determined will assist consumers in making purchasing decisions or in using such products, and will not be unduly burdensome to manufacturers.[21] Specifically, the label includes a yearly energy cost range for the recommended room size, CADR, and IEF. The recommended room size is based on categories DOE applies in their regulations: small (15–154 sq. ft.), medium (155–235 sq. ft.), and large (236 and greater sq. ft.) room sizes.[22] The proposed label also includes the following explanatory text: ''The Clean Air Delivery Rate is based on the removal of particulate matter that is 2.5 micrometers wide or smaller ($PM_{2.5}$ CADR).'' Additionally, the label includes a tertiary disclosure, the model's efficiency rating (the IEF), which should help consumers understand the product's energy use. These secondary and tertiary disclosures help consumers identify models with the appropriate capacity for their needs and facilitates an apples-to-apples comparison of the energy costs of relevant models. Manufacturers should not face any undue burden in disclosing this additional information because this type of information (*e.g.,* efficiency ratings) is readily available from DOE-mandated test results, and manufacturers already include such information on most EnergyGuide labels for other products.

Under this proposed Rule and consistent with EPCA's requirements, manufacturers must use the new DOE test procedure to generate information on the label. In issuing its test procedure, DOE has resolved or addressed the various commenter issues concerning testing.[23] Given DOE's expertise in setting such procedures, the Commission defers to its conclusions. In addition, the Commission will set a labeling compliance date consistent with DOE's Tier 2 standards requirements (Dec. 31, 2025), as suggested by the Joint Commenters. This date will provide the FTC an opportunity to gather and publish range information for the new label based on reporting to DOE or other available sources prior to the compliance date, and otherwise provide the time necessary for manufacturers to create and incorporate the new labels on packaging. Consistent with DOE requirements, the proposed reporting date for these products is December 1 of each year. The Commission seeks comment on all aspects of this proposal. Among other things, commenters should address the content, placement, and timing for the new label, as well as any other relevant issues.

C. Clothes Dryers

Background: EPCA designates clothes dryers as covered products in 42 U.S.C. 6292. In 1979, however, the Commission declined to require labels for these products after finding competing models on the market had a limited range of energy use.[24] In 2014, the Commission reconsidered that decision, and again concluded

[18] The Joint Commenters stated that a standard first-order differential equation that includes these contributions is utilized for the calculation, and that is summarized as: Room Size (square feet – ft^2) = cigarette smoke CADR × 1.55; Room Size (square meters – m^2) = Room Size (ft^2) × 0.093. They also explained that the maximum allowable CADR that can be measured by the ANSI/AHAM AC–1–2020 method in the chamber is 600, so the maximum room size that the standard can confidently predict performance would be a room of 930 ft^2 (86.4 m^2). For modeling of suggested room size, AHAM assumes a room height of 8 feet and the air cleaner producing 4.8 air changes per hour of cleaned air.

[19] Madison IAQ argued the label should not apply to Incidental Air Cleaning products, which include products that meet DOE's ''air cleaner'' definition but provide an additional function unrelated to air purification, such as a vacuum cleaner, fresh air ventilators, range hood (ducted or non-ducted), refrigerator, or desiccant dehumidifier, and whose air purification function is incidental to its other functions. The Commission notes that DOE has stated '' 'incidental air cleaning products' do not meet the definition of an air cleaner as defined in 10 CFR 430.2.'' 88 FR 14014, 14018 (Mar. 6, 2023).

[20] *See* ''2023–03 Technical Support Document: Energy Efficiency Program for Commercial and Industrial Equipment: Air Cleaners, March 2023,'' Chapter 3, *https://www.regulations.gov/document/EERE-2021-BT-STD-0035-0024.*

[21] 42 U.S.C. 6294(c)(5).

[22] 88 FR 21752, 21766 (April 11, 2023) (conservation standards); 88 FR 14014, 14036–14037 (Mar. 6, 2023) (test procedure); 10 CFR parts 429 and 430.

[23] *See* 88 FR 14014 (Mar. 6, 2023).

[24] 44 FR at 66469. Under EPCA, the Commission must prescribe labels for dryers unless it finds labeling would not be technologically or economically feasible. 42 U.S.C. 6294(a)(1). When it promulgated the Rule in 1979, the Commission, after examining the statute and statutory history, concluded ''that Congress['s] intent was to permit the exclusion of any product category, if the Commission found that the costs of the labeling program would substantially outweigh any potential benefits to consumers.'' 44 FR at 66467–68.

efficiency varied little across available models.[25] Although the Commission recognized emerging heat pump models used less energy than conventional dryers, few, if any, such models were available in the U.S. at the time. Now, however, heat pump models appear to be more prevalent in the U.S. market. The ANPR, for example, noted the U.S. Environmental Protection Agency (''EPA'') ENERGY STAR website (*www.energy.gov*) lists about two dozen heat pump models as qualifying under that program.

Comments: Commenters split on whether consumers would benefit from an EnergyGuide label for clothes dryers. Some opponents of a label asserted it would provide limited benefit to consumers because there is little variation in energy use among models. Specifically, AHAM and Whirlpool contended available DOE data suggests most models largely cluster into three groups: (1) those just meeting current DOE standard levels, (2) those meeting the ENERGY STAR Clothes Dryer Version 1.1 specification levels, and (3) those qualified for ENERGY STAR 2023 ''Most Efficient'' designation. According to AHAM data, only three percent of shipments and nine percent of electric standard dryer models fall between the DOE energy conservation standard (group 1) and the ENERGY STAR level (group 2). Further, only two percent of shipments outperform the ENERGY STAR (group 3). In short, AHAM asserts available models largely fall into ''two clumps—either ENERGY STAR or not.'' Thus, ENERGY STAR designations already provide the information needed to make informed purchasing decisions. Whirlpool added the FTC cannot demonstrate this variation is great enough to assist consumers in their purchase decisions, and that labeling benefits outweigh the burden associated with manufacturers developing and applying labels.

Other commenters disagreed. The California IOUs, for example, supported ''a label that can easily differentiate the annual operating costs between products.'' It recommended the label include energy costs as the primary disclosure, and a list of the underlying assumptions used to calculate such information, including clothes drying cycles (per week), utility prices, and test load sizes. In addition, Earthjustice asserted, dryer labels ''may deliver the greatest aggregate consumer benefits.'' Citing EPCA's labeling provisions and past FTC consideration of the issue, it argued, because ''FTC has not found—nor could it find—that labeling clothes dryers would not be technologically or economically feasible, labels are required.'' Moreover, Earthjustice argued the past FTC concerns over multiple DOE test procedures are no longer a barrier to labeling.[26] Finally, according to Earthjustice, energy efficiency advances have led to significant energy use variation among current clothes dryer models since the FTC last examined the issue.

Electrolux, a manufacturer of clothes dryers, also expressed support for a dryer label, provided manufacturers have at least a year to comply. The company noted that, while vented dryers still account for about ninety percent of models, other options are steadily increasing. According to Electrolux, these newer products, which use emerging technologies found in heat pump and condensing models, use less energy, though with some increase in drying time. Further, even for traditional vented dryers, the variation between the least and most efficient models continues to widen. In the absence of an EnergyGuide label for these products, Electrolux explained, consumers have difficulty making informed decisions about the true costs and benefits of the new technology. Electrolux additionally explained manufacturers typically represent the DOE minimum or ENERGY STAR minimum dryer energy levels in marketing because without a requirement to disclose detailed, point-of-sale energy information, little incentive exists to do otherwise. In Electrolux's opinion, an energy label would encourage more accurate disclosures. Electrolux provided sample labels featuring the Combined Energy Factor (''CEF'')[27] as the primary display because it ''is the standard metric of the official energy test procedure and used by the DOE to regulate the dryer energy.'' Finally, Electrolux stated labeling will add ''significant cost burden,'' which could be mitigated by using paperless labeling.

The California IOUs recommended the dryer label include information about clothing samples used in the test in addition to the test load size to ensure consumers understand the testing conditions. They also urged that the label include the dryer cycle time from a reputable source such as the ENERGY STAR program because that information is important to some consumers. Additionally, they recommended the label contain two ranges, one for the model class (*e.g.,* vented or ventless) based on similar features, and another combining all model classes.

Finally, the California IOUs explained the DOE test procedure for automatic termination control dryers requires re-running the test using the highest dryness level setting if the final moisture content (''FMC'') from the first test cycle using a default, ''normal,'' or ''medium'' dryness level setting is greater than two percent. These commenters noted that identifying which dryness setting the test employed would provide consumers useful information.

Discussion: The Commission proposes requiring an EnergyGuide label for dryers. Previously, a lack of variation in energy use among similar dryers limited a label's benefit. However, as commenters indicated, the market has changed and will likely continue to change as the number of high-efficiency models steadily increases. For example, recent ENERGY STAR data lists about 500 standard-size models qualifying for ENERGY STAR. These models ranged in energy cost from about $30 to $96/year with multiple variations within that band.[28] As noted by the commenters, many models currently clump into three categories of energy use. However, in the absence of an EnergyGuide label with specific energy cost estimates, consumers cannot easily gauge the different energy savings yielded by models falling within the same category. Moreover, given the progress of energy efficient technology, the utility of a label will likely increase more in the near future. Finally, the costs associated with labeling these products should be similar to those associated with labeling other showroom products such as refrigerators. The Commission has already determined those costs are not overly burdensome. Accordingly, consistent with the Commission's interpretation of the applicable EPCA threshold, no evidence demonstrates the costs of labeling dryers would ''substantially outweigh any potential

[25] 79 FR 34642, 34659 (June 18, 2014); 80 FR 67285, 67296 (Nov. 2, 2015).

[26] *See* 80 FR at 67296.

[27] CEF is the metric adopted by DOE to measure the energy efficiency of clothes dryers. 76 FR 972–01, 976 (Jan. 6, 2011). CEF is calculated by dividing the weight of the test load (lbs.) by the sum of the electric energy used by the dryer during both standby and drying cycles (kWh). *See* 10 CFR Pt. 430, Subpt. B, App. D1 at Sec. 4.7 and App. D2 at Sec. 4.7; *see also Clothes Dryers Key Product Criteria,* Energy Star, *https://www.energystar.gov/products/appliances/clothes_dryers/key_product_criteria* (last visited July 14, 2023).

[28] Calculated at $0.14/kWh. Out of these ENERGY STAR models, approximately 150 have an estimated yearly cost of approximately $95,300 are at approximately $85, 10 at approximately $75, 3 at $64, and 7 between about $30 and $40. For the most current ENERGY STAR data, see *https://www.energystar.gov/productfinder/product/certified-clothes-dryers/results.*

benefits to consumers.'' 44 FR at 66467–68.

Consistent with labels for similar appliances, the proposed dryer label features annual energy costs as the primary disclosure derived from the DOE test procedure, with a secondary CEF disclosure. The CEF metric provides consumers with a second way to understand energy use by disclosing a rating derived from measuring the energy needed to dry a specific test load, thus augmenting the label's primary yearly energy cost disclosure. The proposal also divides ranges into standard (4.4 cu. ft. or greater) and compact (smaller than 4.4 cu. ft.) size categories, reflecting the DOE size categories for these products. Consistent with similarly-fueled products such as water heaters, the proposed Rule also contains separate ranges for gas dryers and electric dryers because most consumers are likely to be in the market for one or the other and do not comparison shop between those model types.

Finally, consistent with labels for other products and to provide consumers with the basic assumptions behind the label's estimate, the proposed label includes a statement explaining the duty cycle (*i.e.,* the typical yearly usage) underlying the label calculations (*i.e.,* ''approximately 5 loads per week'' based on the DOE requirement of 236 per year).[29]

The Commission also proposes to begin requiring the label when DOE's new test procedure (''Appendix D2'') becomes applicable to all dryers, to ensure consistency across all labeled products.[30] DOE requirements currently allow manufacturers to use one of two different test procedures—Appendix D1 or Appendix D2. By waiting until the test in Appendix D2 applies to all units, the FTC will ensure consistent information on the label from a single test. Once applicable data is available, the Commission proposes to publish ranges and provide manufacturers six months to begin labeling their products.

The Commission, however, does not propose adding additional information to the label regarding clothing samples, cycle time, and models that require two cycles under the DOE test procedure. Such information will crowd the label and may confuse consumers. In addition, the results of the DOE test already reflect the significant costs associated with those models requiring two cycles under the DOE test procedure.

The Commission seeks comment on whether it should have separate range categories for vented and ventless models. Specifically, commenters should address whether consumers are likely to compare models with such features when shopping. Commenters should also address whether an annual energy use number as the secondary disclosure would be more useful to consumers in lieu of the CEF.

D. Miscellaneous Refrigerator Products

Background: DOE has designated miscellaneous refrigerators (''MREFs'') as covered products under EPCA. This category includes coolers (*e.g.,* wine chillers) and combination cooler refrigeration products (*i.e.,* products with warm and cool compartments). Within the category, some similarly-sized models exhibit a significant range of energy use. For example, recent DOE data shows freestanding compact cooler models (those between 3 and 7 cubic feet) use between 100 to 205 kWh/yr.[31] Moreover, DOE currently has test procedures and standards for these products.[32]

Comments: Commenters addressing MREFs generally supported or did not oppose labeling these products. For example, Earthjustice noted DOE has found significant variation in the performance of currently available models. Specifically, models for the most common type—freestanding compact coolers with similar capacities—range from ''200 kilowatt hours per year down to half that amount.'' AHAM, which did not oppose labeling, agreed MREF labels would assist consumers in making purchasing decisions.

Discussion: The Commission proposes requiring labels for miscellaneous refrigerators. As discussed above, evidence suggests labeling will aid consumers in their purchasing decisions. In addition, no evidence suggests MREF labeling would be economically and technologically infeasible. The proposed label is consistent with the freezer label (*i.e.,* yearly energy costs, a single range, and a secondary disclosure of annual energy use). The Commission proposes a single table of ranges based on several capacity categories. The MREF proposal also adopts the placement requirements for refrigerators and freezers. Finally, the Commission seeks comment on an appropriate compliance date for the new labels.[33]

The Commission seeks information on whether a typical consumer shopping for such products is likely to consider both ''built-in'' and ''freestanding'' models, and if so whether the proposed categories should be combined.

E. Portable Electric Spas

Background: The Commission's ANPR sought comment on labeling for portable electric spas (*e.g.,* hot tubs). In February 2022, DOE published a tentative determination that portable electric spas qualify as a covered product under EPCA and followed with a final coverage determination in September 2022.[34] DOE estimated more than 3 million households in the U.S. operate portable electric spas regularly, using an estimated energy consumption of 1,699 kWh/yr per household (approximately $238 per year).

Comments: Commenters addressing portable electric spas generally supported labeling these products. The California IOUs, for example, noted that, unlike many showroom appliances, electric spas currently do not fall under the ENERGY STAR program, which makes identification of the most efficient spas ''more challenging when shopping online or on the showroom floor.''

Most commenters focused on the timing of potential labels in light of ongoing DOE regulatory efforts. For example, Rheem, the Pool & Hot Tub Alliance (''PHTA''), the International Hot Tub Association (''IHTA''), and the California IOUs recommended the Commission require labels after DOE finalizes its coverage determination, test procedures, and standards. According to PHTA and IHTA, industry members will need an opportunity to examine the final DOE test procedure before providing ''fully-informed'' comments on label content such as energy costs, consumption, and efficiency.

With regard to label placement, PHTA and IHTA recommended the Rule follow industry standard ''APSP–14 Section 7,'' which states: ''The spa shall be marked by the manufacturer . . .

[29] *See* 86 FR 56608, 56644 (Oct. 8, 2021).

[30] *See* 10 CFR part 430, subpart B, Appendix D2. DOE proposed the required use of Appendix D2 for any future amended energy conservation standards in a 2022 proposed rule. 87 FR 51734, 51809 (Aug. 23, 2022).

[31] *See* DOE Compliance Certification Management System, *https://www.regulations.doe.gov/ccms.*

[32] Pursuant 42 U.S.C. 6294(a)(3), the Commission has authority to require labels on MREFs that DOE designates as covered products pursuant to 42 U.S.C. 6292(b). DOE issued final test procedures and standards for MREFs in 2016. *See* 10 CFR parts 429 and 430; 81 FR 46768 (July 18, 2016) (test procedure); 81 FR 75194 (Oct. 28, 2016) (standards); *see also* 79 FR 78736, 78737 (Dec. 31, 2014) (FTC request for comments following proposed DOE test procedure).

[33] Commenter Wesolowski asked whether the label would cover the type of powered cooler meant to be plugged into a vehicle. The proposal only covers products included in DOE's standards program.

[34] 87 FR 8745 (Feb. 16, 2022); 87 FR 54123 (Sept. 2, 2022) codified at 10 CFR 430.2.

where readily visible on the shell or front skirt panel of a spa, or the container of the inflatable spa during the point of sale.'' [35]

The California IOUs provided several content suggestions. First, they recommended a five-star rating system. Noting FTC's past decision to reject such a system, based in part over potential confusion between a five-star rating system and ENERGY STAR disclosures, they argued such considerations would not apply to spas because of their absence from the ENERGY STAR program. They also recommended the FTC sort spas by volume to ensure the labels' ranges compare similarly-sized models. Finally, they suggested the label prominently feature the tested ambient temperature ''so consumers can easily discern the difference between the tested temperature and their climate conditions.''

Discussion: The Commission proposes requiring EnergyGuide labels for portable electric spas. Available information suggests labeling for these products would assist consumers in their purchasing decisions. For example, DOE has found that ratings of certified portable electric spas in data collected by the California Energy Commission ''demonstrate significant variation in the total power consumption among different models of standard, combination, and exercise spas that are currently available.'' [36] Additionally, no available information suggests labeling will pose burdens significantly outweighing the benefits.

As with most other labeled products, the proposed label's content reflects the information generated by the DOE test procedure.[37] DOE published its final rule establishing its test procedure on June 13, 2023.[38] As several commenters noted, this procedure only measures standby heating costs for spas, not other operating costs (*e.g.,* water circulation, lights, etc.). However, because standby heating costs account for the large majority of the product's energy use, the Commission finds the usage numbers produced by the DOE procedure will be beneficial to consumers. To ensure consumers understand this limitation, the bottom of the proposed label states: ''The cost estimate reflects only the heating cost of this model and does not include other aspects of operation such as water circulation, filtration, or lights.''

Additionally, consistent with the DOE test, a model's ''estimated yearly heating cost'' would serve as the label's primary disclosure and reflect the estimated cost associated with continuous standby heating throughout the year. Specifically, the standard cost information on the bottom of the proposed label states: ''This label's heating cost estimate is based on continuous heating throughout the year and a national average electricity cost of [__] cents per kWh.'' The proposed label also contains a smaller, secondary disclosure stating ''Energy Used'' in watts to assist consumers who are interested in comparing the respective watts used by the hot tub on standby and by other energy-consuming products in their home. Finally, the proposed Rule requires disclosures of ''fill volume'' to provide a key underlying metric behind the energy use disclosure.[39]

The Commission seeks comments on whether the Rule should require such a capacity disclosure and, if so, whether ''fill volume'' is an appropriate metric. In addition, given the marked difference in the size and functionality of spas, the Commission requests commenters to address whether the Rule should contain separate range categories for spas, separated by capacity and/or spa type (*e.g.,* standard and exercise spas). The Commission also seeks information on the appropriate placement for the label (*e.g.,* on the product itself, on packaging, or included inside the packaging, etc.), whether these products are typically displayed in retail brick-and-mortar stores, and, if so, whether they are displayed outside of packaging. Finally, commenters should address whether retailers should have a role in displaying the spa label, similar to the proposal in this document for appliances (*see* Section V *infra*).

F. Residential Ice Makers

Background: Consumers can purchase residential icemakers in various configurations, including portable, non-portable, and uncooled storage. DOE research has found residential ice makers consume a significant amount of energy, and that there are significant energy use differences both across and within these configurations.[40]

Comments: Commenters specifically addressing residential ice makers opposed labeling for these products.[41] According to AHAM and Whirlpool, the DOE commercial test procedure is not appropriate for residential models. According to these commenters, the residential models, in contrast to commercial models, generally have lower capacity, are stand-alone, and are used infrequently in low volumes. Further, according to Whirlpool, little data exists, either from DOE or manufacturers, to compare the energy efficiency of residential ice maker models, even using the automatic commercial ice maker test procedure.

Moreover, in the DOE proceeding, AHAM opposed DOE's four-pound-per-day usage metric, arguing reliance on the number would mislead consumers because no data supported the assumption behind it. Instead, AHAM urged DOE to study average daily ice use for the residential products and use those assumptions to determine whether standards are justified under EPCA.[42]

Discussion: The Commission does not propose a label for residential ice makers at this time. Given the uncertainties regarding energy use, the absence of a test procedure specifically tailored to residential (consumer) models, and ongoing concerns expressed by commenters about the applicability of the commercial test to residential models, the Commission will continue to monitor developments related to these products and revisit the issue if warranted.

G. Humidifiers

Background: Consumers use residential humidifiers either to increase or maintain the humidity levels in all or parts of the home or to ease illness symptoms.[43] There are currently no DOE or EPA ENERGY STAR

[35] According to the California IOUs, portable electric spas sold in California after June 2019 must bear a consumer-facing label displaying the spa's average standby power usage. Cal. Code Regs. tit. 20, Sec. 1602 and 1607. These commenters urge FTC to use it as the basis for a national spa label.

[36] 87 FR 8745, 8747 (Feb. 16, 2022).

[37] According to analysis cited by DOE, the mode of operation measured in the test procedure represents approximately 75 percent of the energy consumed by a portable electric spa and as high as 95 percent in some cases. 87 FR 63356, 63361 (Oct. 18, 2022).

[38] 88 FR 38600 (June 13, 2023).

[39] As the California IOUs indicated, the Commission considered and declined to adopt a five-star labeling system for reasons fully explained in an earlier proceeding. *See* 72 FR 49948 (Aug. 29, 2007). The Commission declines to revisit those issues here.

[40] *See* Preliminary Technical Support Document EERE–2011–BT–STD–0043–0024, Section 7.2.3 and Table 7.2.4, DOE, *https://www.regulations.gov/document/EERE-2011-BT-STD-0043-0024.*

[41] Some commenters (*e.g.,* California IOUs) generally supported labeling for new product categories, like residential ice makers, without further elaboration.

[42] AHAM further argued that, since DOE has designated all ice makers, including residential icemakers, producing less than 50 pounds per day as ''commercial'' products, such products fall outside of the FTC's authority to require labels only for ''consumer products'' under EPCA. *See* 87 FR 65856 (Nov. 1, 2022); 42 U.S.C. 6291(1); 42 U.S.C. 6294(a).

[43] *See* 42 U.S.C. 6294(a)(6) (general labeling authority). For dehumidifiers, EPCA contains a specific prohibition for an ''Energy Guide'' label requirement. 42 U.S.C. 6294(a)(5)(C).

standards or test procedures for these products. However, a 2012 ENERGY STAR report found there were differences in energy consumption among competing humidifiers, particularly for whole-house models.[44] The report also stated there was ''very little, if any, correlation between humidification capacity (in square feet) and watt rating.'' The report concluded consumers could collectively save an estimated 3.4 terawatts of electricity over the lifetime of these products by choosing energy-efficient humidifiers.

Comments: The two commenters addressing this product in detail opposed labeling. Specifically, AHRI and AHAM argued labeling was not appropriate due to the lack of DOE (or industry) test procedures or standards, and the lack of evidence labeling would aid consumers.[45]

AHRI disagreed with conclusions in the 2012 ENERGY STAR report. It attributed EPA's findings to ''a lack of understanding of adiabatic and steam product operation.'' In contrast to the report, AHRI argued that the energy input for the two primary types of systems—steam and adiabatic—are ''quite comparable,'' and observed little variability in the energy input between current brands/models.[46] Finally, no commenter identified a separate test procedure suitable for humidifier labeling or otherwise provided specific support for labeling these products.

Discussion: The Commission does not now propose requiring labeling for humidifiers. Doing so would be premature in the absence of a DOE test procedure or a suitable substitute. The Commission acknowledges the inconsistencies between the industry comments and the 2012 EPA report regarding relative energy use. However, in the absence of an applicable test procedure, there is no need to now address this issue further. The Commission will continue to monitor developments related to potential labeling for these products.

H. Miscellaneous Gas Products

Background: In February 2022, DOE tentatively determined miscellaneous gas products, such as decorative hearths and outdoor heaters, qualify as covered products under EPCA.[47] These products include fireplaces, fire pits, and similar products that have decorative purposes but can also provide heat. DOE proposed defining ''decorative hearth product'' as gas-fired appliances that simulate a solid-fueled fireplace or present a flame pattern. DOE's proposed definition includes products: (1) designed for indoor and/or outdoor use; (2) not designed to be operated with a thermostat; (3) not designed to provide space heating to the indoor space in which they are installed; and (4) not designed to provide heat proximate to the unit. DOE estimates suggest these products can generate substantial energy costs for consumers.[48]

Comments: Commenters specifically addressing miscellaneous gas products generally opposed labeling requirements, arguing any such requirements are premature given ongoing work related to defining categories, establishing test procedures, and setting standards. For example, AHRI stated the ''product class is vast, varied, and only recently covered by DOE.'' Further, the test procedure development process has not begun. AHRI also discussed the broad array of products in this category and identified industry test procedures, some of which do not contain provisions for efficiency metrics.[49] Similarly, several natural gas industry organizations (the ''Group'') argued because DOE has not completed its work on establishing efficiency levels and test procedures for several of these products, a labeling rule would be premature and could risk ''communicating incomplete or inaccurate information to a consumer.'' The Group also noted the DOE coverage determination for these products is currently undergoing a legal challenge, which could alter their status under EPCA.

In addition to these DOE-related concerns, TIC Council cautioned an EnergyGuide label may suggest these products are energy-efficient.[50] Finally, AHRI argued, given the variety and different uses of these products, ''it is very difficult to envision a label that would help inform consumers.'' Specifically, according to AHRI, some products are sold by contractors and many as part of new home construction, where consumers are unlikely to see the labels prior to purchase. AHRI also suggested the label would be obtrusive and detract from a product's decorative nature, particularly outdoor products such as patio heaters ''that are integral to the ambience.''

Discussion: The Commission does not now propose labeling requirements for miscellaneous gas products. Given the array of product types and the early stages of DOE test procedure promulgation, the Commission will continue to follow developments for this product category and, if appropriate, address potential labeling at a future date.

I. Cooking Tops

Background: EPCA lists ''kitchen ranges and ovens'' as covered products.[51] In 1979, the Commission decided not to require labels for cooking tops, as well as ranges and ovens, because of the small variability of energy use between models.[52] Recent DOE research, however, found energy consumption for gas cooking top models now may vary significantly depending on burner and grate design. DOE also noted energy consumption among similar electric cooking top models can vary depending on whether the product employs induction or resistance heating or has smooth or coil elements.[53] While DOE withdrew its test procedure for these products in August 2020,[54] in 2022, DOE reestablished a test procedure for conventional cooking tops.[55]

Comments: One commenter, the California IOUs, supported labeling.

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[44] ENERGY STAR Market & Industry Scoping Report: Residential Humidifiers (Oct. 2012), available at *https://www.energystar.gov/sites/default/files/asset/document/ENERGY_STAR_Scoping_Report_Residential_Humidifiers.pdf.*

[45] AHAM argued that 42 U.S.C. 6294(a)(3)(B) prohibits labeling for these products unless there is a DOE test procedure. However, that provision applies only to products DOE has designated as a covered product pursuant to 42 U.S.C. 6292(a)(20). DOE has made no such a designation for humidifiers. The Commission has separate authority under 42 U.S.C. 6294(a)(6) to ''require labeling or other disclosures in accordance with this subsection for any consumer product not specified in this subsection or section 6292 of this title if the Commission determines that labeling for the product is likely to assist consumers in making purchasing decisions.''

[46] AHAM's comment provided a detailed discussion of technical issues related to energy input for steam and adiabatic models. It explained the lack of variation among models stems from the fact that the energy required to change water to humidifying mist is comparable for both types of models and that this energy accounts for most of a humidifier's energy consumption.

[47] 87 FR 6786 (Feb. 7, 2022).

[48] *See* 87 FR at 6792. DOE also discussed these general issues in 2013. 78 FR 79638, 79640 (Dec. 31, 2013).

[49] In its comments, AHRI discussed vented decorative gas appliances, various gas fireplace appliances, outdoor decorative gas appliances, covering gas pits, fire tables, and gas-fired outdoor infrared patio heaters.

[50] Without further elaboration, commenter Merriam suggested adding space heaters in addition to the Miscellaneous gas products (''Hearth Products'').

[51] 42 U.S.C. 6292(a)(10).

[52] 44 FR 66466, 66469 (Nov. 19, 1979) (''Since the substantial costs of a labeling requirement would not produce corresponding consumer benefits, the Commission has determined that labeling of kitchen ranges and ovens would not be economically feasible.'').

[53] 81 FR 60784, 60800–02 (Sept. 2, 2016).

[54] 85 FR 50757 (Aug. 18, 2020).

[55] *See* 87 FR 51492 (Aug. 22, 2022)); 86 FR 60974 (Nov. 4, 2021) (results of round robin testing).

Specifically, this group urged the Commission to include on the label the cooktop's duty cycle using the DOE test procedure (418 kWh/yr at 31 minutes per cycle) in a way that helps consumers relate these use assumptions to their personal use.

Most commenters addressing this issue, however, opposed labeling, raising various questions about the viability of labeling these products.[56] For example, AHAM and Whirlpool argued EnergyGuide labels for gas cooking products are premature because stakeholders have identified several outstanding concerns with the recently finalized test procedures. Specifically, they asserted the DOE test procedure is ''highly variable'' (*i.e.,* raises repeatability and reproducibility concerns) and thus may not ''provide a 'good basis' for consumers to compare cooktops.'' In addition, AHAM and Whirlpool noted, because the DOE procedure is new, limited data is available from which to determine whether an adequate differentiation among products exists to warrant labeling. Based on its initial review, AHAM stated there may be little difference in energy use among the products but is working to collect data to further evaluate test results. Whirlpool added that DOE's testing does not provide information about the efficiency of a broad range of representative models in the market.

AHAM also asserted conducting DOE's current test is unduly burdensome, and thus labeling would not be economically feasible. Further, because there is no test procedure for ovens, AHAM suggested labels applied only to cooktops (which are often attached to ovens) will confuse consumers. Finally, AHAM asserts conflicts with Canadian test procedures could cause further confusion; and therefore, the FTC should wait ''until such time as the two countries harmonize their requirements.''

Discussion: At this time, the Commission has insufficient information to change its previous determination. Specifically, given the absence of data demonstrating variability of energy use among competing products, the Commission will continue to follow developments for this product category and, if appropriate, address labeling at a future date.

J. Additional Lamps (Light Bulbs)

Background: The Rule's Lighting Facts label currently covers an array of lamp (*i.e.,* light bulb) types and allows manufacturers to use the label on lamp products not covered by the Rule. The Rule specifically covers general purpose and specialty consumer lamps used in typical household applications, and excludes products where labeling is unlikely to provide substantial benefit. In the ANPR, the Commission sought comment on whether to cover lamp types not currently specified in the Rule, particularly 25-watt incandescent bulbs and full color ''tunable'' lamps with adjustable color.[57]

Comments: Commenters specifically addressing lamp labeling opposed expanding existing requirements. Specifically, the National Electrical Manufacturers Association (''NEMA'') asserted these lamp types (*e.g.,* 25-watt incandescent and lower) are often used in commercial applications where their use varies significantly from typical household lamps and are not typically purchased by consumers as direct replacements for ordinary light bulbs.[58] In addition, they contend that ''tunable'' adjustable-color lamps provide benefits beyond those of general service lamps, so their application and use are not comparable to that of labeled lamps.

Discussion: Commenters did not identify a compelling reason to expand the existing coverage of the lamp label. The label already covers most consumer lamps, and the Commission lacks evidence that expansion to include narrow categories would generate significant benefits. Moreover, using assumptions applicable to most residential bulbs to label commercial lamps could lead to consumer confusion and outright deception. Therefore, at this time, the Commission does not propose expanding the Rule's scope to cover additional types of lamps.

V. Issues Relating to Existing Products

Several comments raised issues about products already labeled under the Rule. These included proposals to (1) change the clothes washer label content, (2) include handwashing information on the dishwasher label, (3) eliminate range information on television labels, and (4) improve the Rule's provisions for water heaters, pool heaters, and boilers.

A. Clothes Washer Labels

Background and Comments: Two commenters recommended changing the clothes washer label to include information about a model's ability to reduce moisture (*e.g.,* the final moisture content (''FMC'') of the washed load) and thus ultimately use less energy. According to these commenters, the absence of this information misleads consumers regarding the true energy cost of washing clothes because more moisture at the end of the cycle means the dryer requires more energy. The California IOUs, which argued for incorporating drying energy costs into the current yearly energy cost estimate, provided data demonstrating significant differences in FMC among washers, ranging from about 31 to 51 percent. Their analysis showed these differences caused corresponding substantial variations in estimated yearly energy costs after factoring in drying energy.

Similarly, Electrolux commented the current label's annual energy consumption (''AEC''), *i.e.,* yearly energy use in kWh disclosure does not properly assist consumers because it is missing the ''largest component of energy efficiency for washers, the energy to dry the remaining moisture left in the washer load.'' According to Electrolux, the ability to remove moisture varies significantly among models for different classes, sizes, and brands.

To address these concerns, Electrolux proposed a modified label displaying the DOE standard for clothes washers using an Integrated Modified Energy Factor (''IMEF''), a metric which accounts for energy needed to remove remaining moisture.[59] It further recommended displaying an accompanying range showing the best and least efficient washer range for IMEF across all washers and classes. According to Electrolux, because the DOE standard accounts for drying energy, it provides a more accurate way to compare washer models than AEC, which only accounts for washer energy. Under its proposal, the label would display AEC as a secondary disclosure. Alternatively, Electrolux suggested including annual drying cost into the washer's energy cost disclosure, using a

[56] Natural gas industry organizations (the ''Group'') raised similar concerns.

[57] In the past, the Commission has looked beyond DOE's specific lamp definitions, which generally cover products subject to DOE's efficiency standards, to include products designated as ''specialty consumer lamps'' using its general labeling authority at 42 U.S.C. 6294(a)(6). 80 FR 67285 (Nov. 2, 2015).

[58] NEMA expressed support for the existing label's coverage, identifying the label as an example of ''how consistent labeling can support a market change'' and noting its widely recognizable format ''strikes an optimal balance of information provided and accommodations of the physical constraints.''

[59] The Integrated Modified Energy Factor measures the energy efficiency of a clothes washer as the quotient of the capacity of the clothes container divided by the total clothes washer energy consumption per cycle, which includes ''the energy required for removal of the remaining moisture in the wash load.'' 10 CFR Pt. 430, Subpt. B, App. J2.

different cost metric such as ''Effective Energy Cost'' to avoid confusion.[60]

Discussion: The inclusion of information reflecting a washer's ability to reduce moisture content could help consumers with their purchasing decisions. However, it is unclear whether consumers would understand the IMEF disclosure, including its relation to moisture content.[61] In addition, relegating the annual energy cost estimate to a secondary disclosure could undermine the effectiveness of that disclosure. Therefore, the Commission declines to include IMEF on the washer label at this time.

Nonetheless, given the issues raised by the comments, the Commission seeks further comment on whether the Rule should require a disclosure for the additional cost of removing moisture from clothes and other related information, and, if so, how manufacturers should calculate this information and how the EnergyGuide label should present such information in a helpful and not confusing way. For example, manufacturers could derive annual energy cost estimates for moisture removal by multiplying the number of wash cycles per year by the per cycle energy consumption for removal of moisture from the test load. Alternatively, DOE could consider amending its test procedure to specify the means for generating this information.

B. Dishwashers

Background and Comments: The California IOUs recommended including information about the costs of handwashing on the dishwasher label. Specifically, according to these commenters, handwashing dishes uses substantially more energy and water than an ENERGY STAR-rated dishwasher. They also recommended the label include a dishwasher's cycle time using DOE test results, given its importance to consumers.

Discussion: The Commission does not propose amending the dishwasher label to reflect handwashing costs. The California IOUs have not identified relevant data demonstrating that dishwasher shoppers want to compare the cost of handwashing to the machine's operating cost, and the FTC is unaware of any such data. In the absence of such data, the FTC concludes that the disclosure is unlikely to be helpful to most consumers. Further, the additional information would likely clutter the label, and thus, may detract from its effectiveness. The disclosure also could confuse consumers who may think the label's handwashing costs are associated with the model's operation. Balancing these considerations, a specific dishwasher disclosure is not warranted. However, sellers may present information about handwashing through consumer education materials separate from the label.

Similarly, the Commission does not propose including a dishwasher's cycle time on the label. Although this information, like many other metrics related to the product (*e.g.,* dimensions), may be useful for consumers, it is not clear it is needed to help consumers understand the energy label. Moreover, manufacturers can provide this information through technical specifications in manuals and marketing materials.

C. Television Ranges

Background and Comments: CTA, an association representing television manufacturers, urged the Commission to eliminate comparability ranges for television labels, ''in light of changing technology and online availability of information to consumers.'' Noting FTC's discretion under EPCA to exclude ranges from television labels, CTA argued the ranges are not helpful to consumers for three reasons. First, given rapid changes to available models driven in part by constantly evolving technology, attempts to estimate ranges are futile ''because the data becomes quickly outdated almost as soon as it is set.'' Second, CTA stated well-established resources exist for product comparisons, including consumer and trade publications and product reviews. Third, consumers can already make energy use comparisons based on the most significant element of the EnergyGuide label, the estimated yearly energy cost.

Discussion: Comparability ranges for televisions, while not mandatory under EPCA,[62] make it easier to compare a particular model's operating cost relative to others available in the market, and to see where that model falls in the whole market for similar products. Consumers could perform these tasks with the estimated yearly energy cost disclosure, but that would be significantly more difficult than reviewing ranges on a label because consumers would have to find the energy usage of all comparable models on their own. On the other hand, rapid market changes may quickly render disclosed ranges obsolete while imposing compliance burdens on manufacturers. Further, eliminating the ranges but maintaining the same font and text size for the other information would simplify the label, thus, making is easier to use. Accordingly, the Commission seeks comment on CTA's proposal (see sample label at Illustration 1). Commenters should address the costs and benefits of the proposal, including the timing for such a transition, should the Commission decide to eliminate the ranges.

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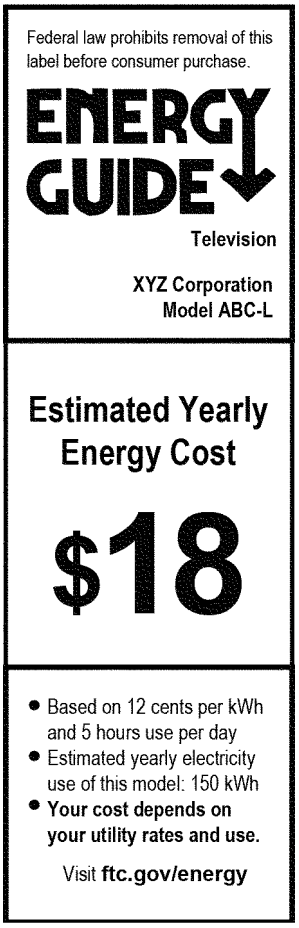

Illustration 1

BILLING CODE 6750–01–C

[60] The California IOUs also recommended the inclusion of a model's cycle time on the label ''when this data becomes available from a reputable source'' because it is an essential consideration for some consumers. According to the commenters, DOE's May 2022 test procedure provides this information.

[61] In addition to the IMEF, the DOE standard cited in Electrolux's proposal also measures the Integrated Water Factor (''IWF''), which represents the total weighted per-cycle water consumption for all wash cycles in gallons for each cubic foot (or liter) of clothes washer capacity. 10 CFR Pt. 430, Subpt. B, App. J2. Like Electrolux's proposed IMEF disclosure, it is unclear whether consumers would understand an IWF disclosure or use it when making purchasing decisions.

[62] *See* 42 U.S.C. 6294(c)(9) (giving the FTC discretion over labeling requirements for certain covered products, including televisions listed in subsection (a)(2)(I)).

D. Water Heaters

Background and Comments: Rheem, a water heater manufacturer, suggested several label changes for instantaneous (*i.e.,* ''on-demand'') water heaters. First, it recommended allowing manufacturers to affix the label to gas-fired instantaneous water heater packages (instead of the product itself).[63] According to Rheem, since these units frequently operate in visible living spaces, the label may be aesthetically undesirable on the product. Second, it recommended a smaller label for both gas-fired and electric instantaneous water heater packages because the packaging profile for many models is not much larger than the EnergyGuide label itself, leaving limited room for other important product information and advertising. To support its position, Rheem cited Rule provisions allowing smaller labels and different space-saving configurations in other contexts (*e.g.,* television labels and labels in paper catalogs).[64]

Rheem also raised a separate issue about boilers. It observed some boilers operate as combination space/water heaters. The current test procedure, however, does not address these combined functions. Therefore, Rheem recommended the Rule require text stating these products can be used for space and water heating.

Discussion: In response to the comments, the Commission proposes allowing the labels for instantaneous gas models to appear on packaging because of the difficulties in affixing the label to the product itself and the likelihood that few such models are displayed out of the box. Given the packaging size, the Commission also proposes decreasing the size of the labels for both instantaneous electric and gas-fired water heaters by one-third (see Illustration 2) to leave room on product boxes for other important information. This size reduction should not detract from the label's usefulness because the text and font size on the label will be identical to the existing label. Finally, the Commission does not propose changing the label to inform consumers particular water heater models can also be used for space heating. The Commission is concerned that adding this information to the label may cause confusion (*e.g.,* suggesting the label's water heating information applies to the product's space heating operation). However, manufacturers may instead inform consumers about the product's space heating capabilities in statements off the label, on packaging, and its advertising.

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[63] The Rule currently makes this allowance for electric instantaneous water heaters only. 16 CFR 305.13(e)(3).

[64] In addition, Rheem recommended against any label changes that would add information featured on European labels, such as decibel level, demand response capability, and a map indicating how a heat pump water heater will perform in different regions. The Commission has not proposed such changes. Rheem also urged the FTC to work with DOE to ensure labeling requirements are consistent with recent DOE proposals to apply the conservation standards to consumer water heaters. It also recommended a correction to size category references 16 CFR 305.17(a)(9) related to alignment with those in Appendix E. The Commission addressed this issue in a January 2023 Final Rule; correction and correcting amendment. *See* 88 FR 1135 (Jan. 9, 2023).

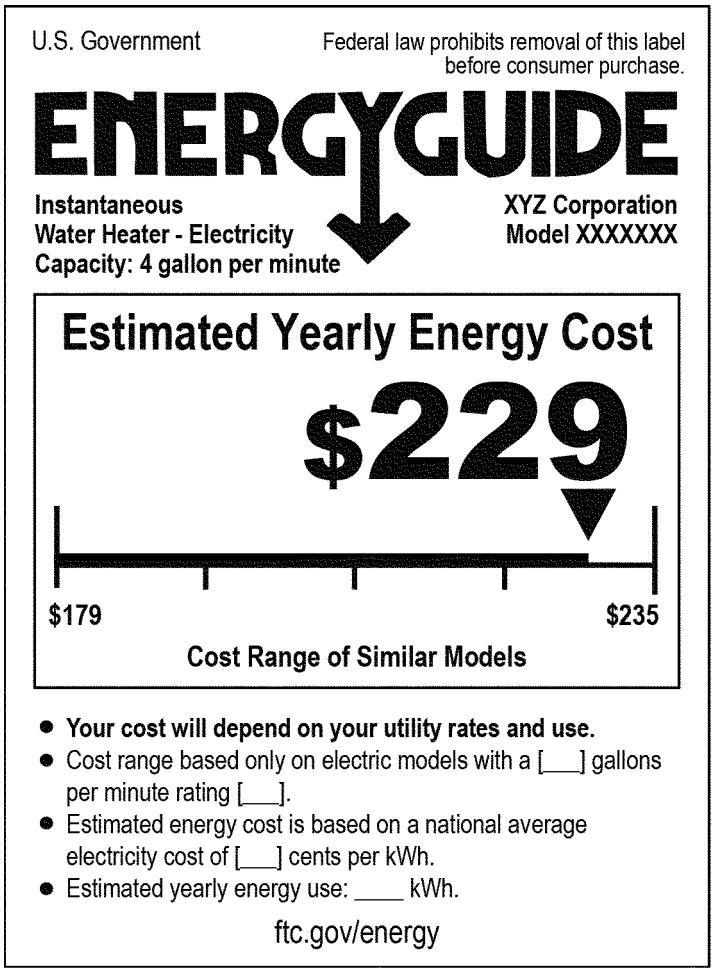

Illustration 2

BILLING CODE 6750–01–C

E. Pool Heaters

Background and Comments: The Rule currently requires manufacturers to label pool heaters using thermal efficiency as the primary disclosure. In Rheem's view, the current label does not provide consumers with the information necessary to make informed purchasing decisions because it does not include fuel type, capacity, and a comparability range of either efficiency or annual energy cost. Rheem noted in the past the FTC has refrained from requiring additional information due to limitations in the DOE's pool heater test procedure.[65] However, Rheem now explains DOE has updated its test procedure to include a new efficiency metric (integrated thermal efficiency) and to provide a method to derive other important information such as estimated annual energy costs. Rheem did note DOE's updated procedure lacks a clear delineation of capacity.[66] Therefore, Rheem urged the FTC to urge DOE to include appropriate capacity metrics in its final rule for consumer pool heaters.

Discussion: The Commission seeks comment on amending the pool heater label to include an annual operating cost disclosure and additional information (*e.g.,* fuel type, capacity, etc.) consistent with other EnergyGuide labels.[67] Commenters should also address any specific issues related to capacity disclosures for these products. Additionally, since DOE's changes to the pool heater standards will not become effective until 2028,[68] the Commission seeks comment on whether any label changes should coincide with this DOE compliance date.

F. Boilers

Background and Comments: As discussed below, several boiler manufacturers commented on labeling issues for their products. Four manufacturers recommended significant changes, and two others opposed any changes to the Rule's current approach.

Specifically, manufacturers WM Technologies and Marley Engineered Products (together, ''The Marley Company'') recommended allowing manufacturers to consolidate energy-related information for multiple models within a product family onto a single label, in order to minimize manufacturers' burden of maintaining multiple model-specific labels as required by the current Rule. Similarly, manufacturers Crown and Burnham (''Crown'') recommended replacing the current model-specific labels with a common QR code or similar feature directing consumers ''to an on-line source where the Energy Guide 'label'

[65] *See, e.g.,* 72 FR 49948, 49953–54 (Aug. 29, 2007).

[66] Rheem noted DOE regulations require manufacturers to certify the input capacity of each gas-fired pool heater model. 10 CFR 429.24(b)(2). However, DOE's ongoing energy conservation standards rulemaking proposal would effectively require heat pump technology on these products. Since heat pump pool heaters move heat instead of generating heat, DOE argued output capacity may be a better capacity metric than input capacity.

[67] Most EnergyGuide labels required by part 305 routinely display some sort of capacity figure.

[68] 88 FR 34624 (May 30, 2023).

for that model could be easily found (*e.g.,* the AHRI Directory).'' Crown observed consumers do not purchase boilers in showrooms because the choice of an appropriate boiler requires the expertise of a contractor. Boilers operate as part of a system that includes fuel, heating capacity, heating medium, operating water temperature range, and venting. In Crown's view, only trained professionals have the expertise to weigh these factors to determine which boilers can operate safely, reliably, and efficiently in a particular home. Thus, requiring manufacturers to include model-specific energy consumption data on the boilers themselves makes little sense. Faced with a choice provided by contractors, Crown explained consumers often research boiler models and brands prior to purchase, but do so using on-line resources and/or printed literature. Accordingly, Crown stated that replacing the current model-specific label with a feature directing consumers to an online resource would be more helpful to consumers.

Additionally, Crown recommended eliminating the requirement that labels be affixed to boilers. Instead, it suggested the Rule allow manufacturers to include the label as a paper insert or tag either hung on the boiler or inserted in an envelope with the manual and other documentation. Crown noted modern boilers are much smaller than past models and finding space for the label ''has been a growing challenge'' adding cost and assembly time. In its opinion, the EnergyGuide labels not only ''detract from appliance appearance'' but ''more importantly, compete for consumer attention with labels that convey important post purchase information, including safe installation and operation. Such a change would also address challenges with ensuring the appropriate materials and adhesives are employed to keep labels on products.

Other manufacturers did not support any changes to the current label. Bradford White (''BWC'') explained it has not received any feedback from customers, or product end-users, to indicate the current label fails to clearly communicate important information to consumers. In addition, BWC observed the current information on labels aligns with DOE's requirements. Rheem also did not recommend any changes to existing boiler labels.[69]

On a separate issue, the Marley Company and Crown recommended eliminating inconsistencies in the requirements for labeling boilers and furnaces. The Marley Company noted installers can configure both oil and gas boilers for capacities different from the one preset by the manufacturer, but the Rule currently allows only labels for oil boilers to list information for these alternative capacities. It recommended eliminating this inconsistency by allowing labels for both oil and gas boilers to include alternative capacities information. In addition, Crown noted § 305.20(f)(11) requires manufacturers to use the boiler's lowest attainable AFUE rating to label multiple-input boilers with more than one input nozzle to be installed in the field. In contrast, §§ 305.4(a) and 305.20(f)(13) require manufacturers to label the same boilers with the AFUE rating for input capacity set by the manufacturer. Crown also explained these sections could be read to set different labeling standards for multiple-input boilers and for furnaces when ''no logical reason'' justifies the difference. Crown proposed language for § 305.20(f)(11) and (13) to eliminate these apparent discrepancies.

Discussion: The Commission does not propose changing the general content of existing boiler labels.[70] Consistent with comments from BWC and Rheem, there is no clear evidence the current label fails to assist consumers in their purchasing decisions. In addition, allowing labels with information for multiple models within a product family would likely crowd the label and make it more difficult for consumers to use.[71] Similarly, moving to a QR-type label would likely erode the label's benefits because it would require consumers to take additional steps to access the information (see further discussion at Section VI *infra*).

The Commission, however, seeks further comment on whether it should amend the Rule's boiler label placement. Specifically, given the concerns discussed above, commenters should address whether the Rule should allow manufacturers to ship the label with the product in lieu of affixing the label to the unit (see also Section VI *infra*). The Commission is not proposing such a change at this time because it lacks sufficient information on whether shipping labels with the product would undermine the label's effectiveness.

Finally, the Commission proposes adopting the proposed language to § 305.20 offered by Crown and other clarifying language to address concerns raised by Crown and the Marley Company regarding discrepancies in labeling requirements for boilers and furnaces (*see* proposed §§ 305.10(h), 305.20(f)(11) and (13), and 305.22(c)). As suggested by the commenters, the proposed amendments adopt a consistent approach for labeling boilers with more than one input nozzle to be installed in the field, clarify that the same standard applies to both boilers and furnaces, and remove an inconsistency in labeling oil and gas boilers and furnaces.[72] Commenters should address whether this clarifying amendment is helpful and appropriate.

VI. Matching Label Format and Location to Consumer Shopping Patterns

In the ANPR, the Commission solicited comments on alternatives to the current ''showroom-ready'' approach. The Commission additionally requested any recent research or data demonstrating when and where consumers typically make purchasing decisions for the types of products covered by the Rule. In this section, the Commission discusses comments regarding current shopping trends and label placement, and proposes new label placement requirements for showroom appliances.

A. Comments on Shopping Trends

Several commenters (*e.g.,* AHAM, Whirlpool, and the California IOUs) highlighted the increasing tendency of consumers to research major appliances online before making a purchase, even when they make the purchase in-store. Moreover, the commenters noted consumers are increasingly comfortable with buying large consumer products without visiting a store. For example,

[69] Rheem also explained, consistent with past FTC positions, an annual energy cost would have limited value to consumers because it is based on national average heating load hours and thus will not adequately represent a consumer's actual operating cost. Therefore, Rheem recommended the Commission retain the efficiency comparability range. In addition, similar to its recommendation for pool heaters, Rheem recommended the FTC work with DOE to include the appropriate capacity metrics in the certification requirements in the energy conservation standard final Rule for consumer boilers. Finally, Rheem noted the cost information link on the label directs consumers to DOE's general database.

[70] In response to Rheem's comment, the proposed amendments also correct a typographical error in the DOE published number for the energy equivalence of No. 2 heating oil.

[71] The Marley Company appears to propose the optional use of labels with information for multiple models for not only boilers but all products covered by the Rule. Because the additional information would tend to crowd these labels as well, the Commission also declines to propose the use of such labels with respect to these other products.

[72] For multiple-input furnaces and boilers with no factory-installed nozzle, the proposed label discloses the lowest AFUE rating obtainable by the system. For those with at least one factory-installed nozzle, the proposed label discloses the AFUE rating associated with the input capacity set by the manufacturer. Regardless of whether the boiler or furnace is fueled by oil, the proposed label may include optional information regarding the product's alternative capacities.

the California IOUs pointed to a 2013 GE Capital study showing 81 percent of consumers research major appliances costing $500 or more online before purchasing, with 88 percent of respondents ultimately making their purchase in-store. They also cited a more recent 2021 study by Bain and Company finding 26 percent of global consumers were ''more willing to buy appliances online than they were prior to the pandemic.'' The California IOUs concluded online information is a ''critical driver for consumer purchases'' but acknowledged most consumers still make their final purchase decisions in physical stores. In their view, these trends highlight the continued need for labels on showroom floors while pointing to the additional utility of QR codes for online research and for providing multilingual information.

In addition, AHAM noted, in 2012, two-thirds of consumers researched models online prior to purchasing an appliance, whereas, in 2021, during the COVID–19 pandemic, ''close to 90 percent of consumers'' conducted such online research, and 80 percent planned to continue such online research after the pandemic.

AHAM and Whirlpool also observed once consumers visit a showroom after conducting preliminary research online, energy efficiency becomes less important to their final in-store decisions.[73] Moreover, according to AHAM, the ENERGY STAR logo, annual energy consumption, and annual operating cost information rank in the bottom half of ''identified characteristics'' by consumers. Instead, consumers focus on other purchase factors, primarily the product's purchase price.

Whirlpool also noted the decrease in the amount of printed information sellers use at the point of purchase and an increase in their use of online information, including information linked through QR codes. According to Whirlpool, many consumers never read point-of-purchase materials nor keep them for future reference. Instead, consumers often expect to access such material remotely through QR codes. Whirlpool further asserted that although some printed material or labels are helpful during product setup or to comply with regulatory requirements, product information is ''increasingly only found online, at no apparent detriment to the consumer.''

Whirlpool's own research found consumers ''noticed and liked QR codes used in retail stores to scan and locate more product information on their appliances.'' Consumers also liked QR codes as an alternative to paper literature and labels, which can be easily lost or not transferred from previous homeowners. Its research found a strong majority of consumers would find a QR code linking to more information online to ''be helpful to their in-store shopping experience.''

Commenter Merriam emphasized how energy-efficient appliances can help meet climate goals and ensure electricity system reliability. In doing so, it highlighted several key points from recent studies on consumers' purchasing decisions. For instance, one European study found annual energy expenditures communicated in the form of a monetary value increased the likelihood consumers would purchase an energy-efficient appliance.[74] Another found consumers tend to focus on a label's ''headline'' and were likely to purchase energy-efficient equipment, especially where the cost of operating the equipment is expensive.[75] Based on this research, Merriam recommended continued use of annual energy costs as the primary disclosure, which ''provide simple and consistent messaging about the range or rating of cost energy savings.''

B. Comments on Label Placement for Showroom Appliances

As discussed below, several commenters offered proposals to restructure the Rule's requirements for label placement and presentation. Generally, manufacturers urged a shift to a virtual or ''electronic label,'' which would provide consumers access to energy information through a QR code link or similar feature. Other commenters argued against any approach eliminating physical labels in stores. Finally, industry commenters urged the Commission to provide adequate lead-time to make any changes necessary to comply with Rule amendments.

Major Showroom Appliances: Commenters offered different opinions about the Commission's approach to labeling major showroom appliances.

Some, particularly Earthjustice and NYSERDA, urged the FTC to ensure labels are available to consumers in stores and to maximize label accessibility. Specifically, Earthjustice argued eliminating showroom labels is inconsistent with EPCA, which states the FTC ''shall require that each covered product in the type or class of covered products to which the [Rule] applies bear a label which discloses'' the information of the sort provided on an EnergyGuide or Lighting Facts label. 42 U.S.C. 6294(c)(1). Further, in Earthjustice's view, the label's ubiquitous presence on covered products ''helps to improve consumers' familiarity with the label.'' Even if a consumer does not see the label until after purchase, its presence increases the likelihood the consumer ''will later become aware of the label and the information it conveys.'' Such ''after-the-fact'' awareness, in Earthjustice's view, increases the likelihood consumers will use the label for future purchases. In addition, NYSERDA argued energy labels are ''most impactful when they can be readily accessed wherever a consumer may be looking for them, be that online, in stores, or in a showroom.'' [76]

In contrast, industry members recommended major changes to the label placement requirements. AHAM, which has long supported a shift from paper to electronic labels, argued the technology and infrastructure is now available to ''easily permit the electronic delivery of label information.'' AHAM noted manufacturers already provide label information online to comply with existing Rule provisions (*see, e.g.,* §§ 305.9, 305.11(a)(5), and 305.27). Therefore, it proposed a transition away from ''outdated'' physical labels to reliance on labels online, citing research indicating consumers examine product information online before going to brick-and-mortar stores for purchase. Specifically, it recommended ''flexible approaches to allow manufacturers and retailers to deliver the label content, in an electronic format to consumers.''

Whirlpool also recommended giving manufacturers flexibility, whether through a QR code printed in product literature (*e.g.,* in a quick start guide), on the packaging for some covered

[73] According to Whirlpool, consumers look for energy efficiency but generally do not want to pay more for it or compromise on product performance. Further, consumers generally do not notice large differences in efficiency once they shop in the stores.

[74] *See* Julia Blasch, Massimo Filippini, & Nilkanth Kumar, ''Boundedly Rational Consumers, Energy & Investment Literacy, & Display of Info. on Household Appliances,'' *Resource & Energy Econ., Recent Advances in Econ. Analysis of Energy Demand—Insights for Indus. & Households,* May 2019, Vol. 56, 39–58, available at *https://doi.org/10.1016/j.reseneeco.2017.06.001.*

[75] Lucas W. Davis & Gilbert E. Metcalf, ''Does Better Info. Lead to Better Choices? Evidence from Energy-Efficiency Labels.'' *J. of Ass'n of Envtl. & Resource Economists,* Sept. 2016, Vol. 3 No. 3, 589–625, available at *https://www.nber.org/papers/w20720.*

[76] Several commenters similarly recommended the Commission ensure labels are available in showrooms for consumers to examine (*see, e.g.,* DuSaint, Ring (also saying the label should be available in the product packaging or literature bag), Wesolowski, Davis).

products, and/or through a label permanently affixed to the product itself in a prominent location. Whirlpool further recommended adding explanatory text to the label directing consumers to a website with information about the product's energy efficiency and operating costs. AHAM emphasized the need for different approaches depending on the product categories (*e.g.,* products displayed in a box compared to unpackaged units displayed on showroom floors). For products displayed in boxes, such as air cleaners, it proposed requiring a QR code. For major appliances displayed on showrooms, AHAM stated its members would ''be open to QR codes on the product and/or on the owner's manual as an option so long as the requirements are flexible.''

AHAM also cited benefits from electronic labeling, arguing a label available online would be more impactful because a consumer's ''appliance purchase journey starts with online research.'' In AHAM's view, printed labels shipped inside appliance units (*e.g.,* clothes washers, dishwashers, and refrigerators) ultimately do not assist consumers because the purchase has already occurred when they see the label. AHAM contends consumers likely discard such labels immediately upon installation. Thus, it concluded a shift to purely electronic labeling would eliminate redundant paper labels, involve few regulatory changes, and ''dramatically reduce regulatory burden and cost'' related to printing, affixing, and shipping labels.[77] It also stressed this change would ''be more sustainable'' because it would dramatically decrease the paper and ink used to comply with the Rule. According to Whirlpool, who agreed that many labels are often discarded without helping consumers, the resources needed to print and ship these labels are a ''very non-sustainable practice.'' [78]

Further, AHAM argued a move to electronic labels would provide consumers ready access to the label content (through, for example, links, QR codes, or apps) in a form and manner that best suits them. In addition, such an approach would give retailers flexibility to present the label content either by printing the label or through an electronic device (*e.g.,* phone, tablet). According to AHAM, an electronic format would also allow manufacturers to easily update labels and make corrections to online content when, for example, the FTC updates comparability ranges. AHAM also urged the FTC to work with Canadian regulators to, for example, align data elements, reporting, and content of labels. It noted that because manufacturers often display the U.S. and Canadian labels back-to-back or side-by-side on the same piece of paper, environmental benefits, burden reduction, and cost savings will be largely lost if only one country shifts to electronic labeling.

Alternatively, should the Commission decline to adopt electronic labeling, AHAM and Whirlpool suggested the Rule require manufacturers to affix labels only to those units designated by manufacturers as showroom models. According to AHAM, manufacturers routinely ship designated ''floor units'' to retailers with special point-of-purchase labels and other material. While this special treatment does not cover 100% of units ultimately displayed by retailers, this process ensures most floor units will have the manufacturers' point-of-purchase information, including labels, applied in the factories. Given this practice, AHAM did not object to a Rule provision requiring physical labels ''for the limited number of major appliance units that are displayed on showroom floors on an as needed basis to reduce waste.'' Accordingly, AHAM stated ''it is possible, without a significant amount of burden, to ship floor units to retailers with labels.'' Whirlpool added that such an approach, while less preferable than a complete transition to electronic labeling, would impose less burden than the current requirements.

According to AHAM, manufacturers lack control over products once they leave the factory and thus cannot address missing labels on showroom floors whether removed intentionally or inadvertently. To ensure labels are present on showroom models, AHAM suggested the Rule affirmatively require retailers to place labels on any floor units that lack a physical label (*e.g.,* replacement floor units, units displayed after the initial production run, or units from which labels have been intentionally or inadvertently removed). Under such an approach, retailers could access all labels online to print and attach them themselves, or request manufacturers to ship (or a local manufacturer representative deliver) printed labels.

In discussing potential retailer requirements, AHAM suggested ways the Commission could minimize retailer burden, including providing flexibility for label materials and attachment methods, requiring manufacturers to ship labels in a ''showroom ready'' state for designated floor models, allowing retailers to use existing electronic labels accessed through DOE's website, and ensuring retailers have adequate time to comply with any new requirements. Similarly, Whirlpool recommended that the FTC reduce the Rule's format and attachment requirements for retailers since certain provisions aimed at ensuring label durability through the supply chain would not be applicable to retailer-applied labels. In addition, Whirlpool noted retailers may lack the resources to meet the label size, paper weight, and other requirements of the current Rule.

Other commenters cautioned against loosening the label attachment requirements. Citing past concerns about the absence of labels in showrooms, Earthjustice warned lack of regulatory specificity could lead to non-compliance. In 2015, the FTC added specificity to its regulations governing adhesives and hang tags to address missing labels.[79] Earthjustice argued reducing such specificity now ''would encourage a return to labelling practices that deprive consumers of access to the important information that EnergyGuide labels provide.'' Earthjustice also noted detailed, ''highly standardized'' format and content requirements help ensure EnergyGuide labels can be readily distinguished ''from a variety of other text and images that may be present on display models or product packaging.''

Televisions: CTA, an association which represents television manufacturers, recommended the Commission allow electronic labeling for covered products incorporating electronic displays. Similar to AHAM, CTA argued a physical label requirement is no longer necessary because energy cost information is widely available online and frequently used by consumers. Therefore, CTA urged the Commission to allow sellers to display information electronically. According to CTA, this ''may involve the presentation of the EnergyGuide disclosure on the product's display or screen retrievable on command.'' According to CTA, such electronic labels would allow consumers to both view the label at the time of purchase,

[77] According to Whirlpool, such an approach will make future label updates and transitions quicker, easier, and less confusing for manufacturers, retailers, and consumers.

[78] Whirlpool explained that labels printed and shipped with every unit involve ''tremendous cost'' and are an enormous waste of resources, including the paper for labels, the adhesive backing, printer ink, and other supplies (*e.g.,* zip ties, eyelets, and/or string). For example, one manufacturing location wasted about 43,000 pounds of wax paper every single year from the backing used for the label.

[79] *See* 80 FR 67285, 67291–92 (Nov. 2, 2015), codified at 16 CFR 305.

and ''retrieve a TV model's energy use information long after a product is sold.'' For businesses, the electronic label would support the industry's sustainability efforts by reducing ''printed and physical materials.'' In addition, citing recent FCC electronic labeling measures as well as e-labeling in Canada and Australia, CTA noted such an approach would also be consistent with U.S. and global approaches to electronic labeling, or e-labeling, in other contexts.

C. Comments on Labeling for Heating and Cooling Equipment

Commenters also addressed labeling for central air conditioners, heat pumps, and furnaces, products which consumers generally do not purchase directly in showrooms or online but instead buy through their contractors. AHRI, which represents manufacturers of these products, recommended continuing the requirement that labels be attached to products that are still occasionally displayed at a retail store, such as some water heaters. However, AHRI contended labels affixed to products that consumers generally buy through contractors, such as central air conditioners and furnaces, do not help consumers. In fact, it explained these products are generally not available from retail stores.[80] Further, consumers often buy replacement systems in emergency situations and usually purchase whatever the contractor has available, *e.g.,* when a water heater catastrophically fails. In each of these scenarios, the consumer does not view either the product or the label.[81]

Thus, AHRI recommended replacing the physical label with an electronic one. According to AHRI, a QR code link to an online label would reduce compliance costs for manufacturers while still providing key information to those consumers and retailers who want it. Specifically, AHRI recommended requiring smaller QR labels on central air conditioners and furnaces which link to the full EnergyGuide label on a publicly accessible website, such as the AHRI directory. For central air conditioners and heat pumps where appropriate, this smaller label should include regional identification information to easily communicate the DOE regional standards applicable to these products—thus helping contractors and consumers comply with the law.[82] Further, AHRI argued because efforts to comply with the new DOE requirements will result in an extended transition to new labels and potential market confusion, an electronic label, which manufacturers can readily update, would ease the shift to new metrics while reducing confusion.

Rheem, however, expressed a different view. Although Rheem acknowledged the utility of QR codes in helping consumers find current information, it did not support a transition to a QR code or fully electronic label. At the same time, Rheem argued the EnergyGuide label does not need to be attached to the unit itself, noting consumers may not want a visible label if the unit is installed in a living space. Finally, Rheem argued the Rule should not require a showroom label for water heaters, boilers, and pool heaters because only a small portion of the models available on the market are displayed in a showroom.[83] Instead, in its view, online sources of information, and consultation with professional installers offer the best ways to help consumers make informed decisions.

Two water heater industry commenters favored keeping the existing labels. AHRI asserted most manufacturers find value in a physical label and are opposed to transitioning solely to an electronic label. Similarly, BWC, a water heater and boiler manufacturer, opposed any changes to existing labeling requirements for its products. It observed the current labels clearly communicate annual energy cost and use savings information to consumers. It warned any revisions to the EnergyGuide label ''would require a significant undertaking.'' In addition, BWC stated QR codes would be ''largely unnecessary'' because the label information is currently available through other sources, such as AHRI's Directory.[84]

D. Proposed Changes to Label Placement Requirements

To ensure labels are available on showroom appliances and to decrease unnecessary labeling burdens, the Commission proposes several label placement amendments for products frequently displayed in showrooms such as refrigerators, clothes washers, and dishwashers. As discussed below, the Commission does not propose changes to television label placement but seeks comment on whether the proposed requirements for showroom appliances should apply to televisions. Finally, the Commission does not propose any changes for label placement for heating and cooling products but seeks comment on whether the Rule should allow manufacturers to include the label with the product shipment instead of affixing it to the unit itself.[85]

Under proposed § 305.13, manufacturers of refrigerators/freezers, clothes washers, and dishwashers must ship all units with a physical label.[86] However, the proposed requirements for affixing adhesive labels and hang tags to the product itself would only apply to units designated by the manufacturer for showroom display. For all other units, the Rule would require manufacturers to include a paper label with the unit in some fashion (*e.g.,* in the literature bag or another location consumers and retailers can easily see when opening the product's packaging). Additionally, the proposal requires retailers to ensure any refrigerator, dishwasher, clothes washer, or dryer unit they choose to display in a showroom has a label in a location visible to a consumer examining the product. Retailers are in the best position to ensure labels continue to be displayed on their showroom floors. The proposed Rule, however, does not impose any prescriptive label placement or attachment requirements for retailers both because the labels do not need to survive transportation and retailers, under the proposal, would have the obligation to replace any missing labels. In addition, to effectuate the proposed retailer requirements, the proposed Rule requires manufacturers to furnish labels for these appliances to retailers upon request to ease retailer burdens. Given this new responsibility, the proposal

[80] AHRI cited to discussions in earlier rulemakings where the FTC acknowledged the label has little benefit for the present purchase but likely provides benefit for subsequent purchases. *See* 72 FR 6836 (Feb. 13, 2007).

[81] With respect to split system central air conditioners, AHRI also questioned the label's utility even if the consumer were to see it prior to purchase. The label currently displays the efficiency rating for the least efficient outdoor unit-indoor unit combination. According to AHRI, however, the actual installed system may operate at a higher efficiency than the displayed rating. In contrast, contractors and the AHRI Directory can provide more accurate information accounting for a ''matched system rather than the lowest possible efficiency.''

[82] *See also* Daiken's and The Marley Company's comments. In addition to this electronic labeling approach, AHRI suggested the Commission allow a paper label option on the units themselves.

[83] For further discussion of boiler labeling, *see* Section V of this preamble.

[84] BWC also sought clarity regarding the term ''showroom ready'' as used in the ANPR. The Commission clarifies the reference was simply a shorthand to describe current Rule provisions requiring manufacturers to affix a label on every unit in a location that would be visible to consumers examining the product.

[85] In addition, the Commission does not propose changing the efficiency information for central air conditioners. While the label does not (and cannot) predict the efficiency of the specific installed system, it provides consumers with a general estimate of the installed unit's efficiency rating that can be used for comparative purposes.

[86] These changes would also apply to dryers and miscellaneous refrigerators if they are labeled following this proceeding.

provides a year for retailers to comply. The Commission seeks comments on all aspects of this proposal.

For consumers, the proposed § 305.13 helps ensure every appliance displayed in a showroom has an EnergyGuide label, including by requiring retailers to replace labels. However, the proposal does so without imposing unnecessary costs on manufacturers. Specifically, manufacturers would no longer have to affix adhesive or hang tag labels on millions of units that consumers will never see until after the unit is purchased. Instead, with the exception of a small number of showroom-designated units (a tiny fraction of units produced), manufacturers will simply include a paper label with the shipped product. This streamlining should greatly reduce the time involved in affixing individual labels and resources used in the form of adhesive materials, special paper, hang tag material, and other similar supplies without interfering with consumers' access to the label.

The proposal, however, does not allow sellers to substitute a virtual or electronic label (*e.g.,* a QR code) for the physical label.[87] Abandoning physical labels would likely degrade the label's effectiveness and reduce the program's benefits for consumers. Specifically, physical labels disclose all the required information for shoppers on showroom floors. QR codes, in contrast, allow only a self-selected portion of shoppers (*i.e.,* those that have mobile internet access and take the extra effort to retrieve the information online) access to the label. Although industry commenters suggest some consumers ignore in-store labels, eliminating them would deprive other consumers of valuable information they rely upon.[88]

In addition, the Commission does not propose allowing television labels to appear on screen in lieu of physical labels. As the Commission explained in an earlier proceeding, the method for implementing an effective electronic label is unclear.[89] Such a provision would require retailers to display an EnergyGuide label at all times, and the Commission has no evidence regarding the feasibility of doing so. Specifically, if retailers do not continuously power up all their showroom units, the image might appear only periodically. Further, retail staff or consumers may turn off the product's label-displaying mode to provide shoppers with an unobstructed image. Such intermittent display of the label would make it less likely the required information was available to consumers examining products in stores and therefore could significantly reduce the labels' ability to assist consumers in their purchasing decisions. However, given the lack of record evidence, the Commission seeks comment on this issue, including whether the Commission should follow the same approach for televisions it has proposed here for labeling appliances (*i.e.,* requiring manufacturers to place labels only on showroom-designated models and creating a new requirement for retailers to ensure labels on any model they choose to display).

For air conditioners, furnaces, and water heaters, the Commission seeks comment on whether the Rule should allow manufacturers to simply ship a paper label with the product. The Commission recognizes these products generally do not appear in showrooms. Thus, consumers are unlikely to see labels affixed to those products prior to purchase. The Commission does not, however, propose this change in this NPRM because, as the Commission has observed in the past, labels attached to these types of units can help consumers in future purchases.[90] Commenters should address whether this reasoning remains valid. For central air conditioners, commenters should also address whether labels shipped with the product (but not affixed to it) will adequately inform installers about DOE regional standards requirements.

Finally, commenters should address whether the Commission should follow the same approach for televisions it has proposed here for labeling appliances (*i.e.,* requiring manufacturers to place labels only on showroom-designated models and creating a new requirement for retailers to ensure labels on any model they choose to display).

VII. Proposals for New Label Content

Background and Comments: Several commenters recommended the Commission consider ways to provide consumers with climate-related information and other environmental impact data such as full fuel cycle data. For example, NYSERDA recommended including greenhouse gas emissions (''GHG'') information on the labels to help consumers understand the broader environmental impact of their purchases. To convey variability in emissions related to electricity use across the country, NYSERDA suggested displaying a range of emissions based on the average grid intensities collected by the EPA and the U.S. Energy Information Agency (''EIA'').[91]

The National Propane Gas Association (''NPGA''), the American Gas Association (''AGA''), and the American Public Gas Association (''APGA'') (collectively ''the Group'') recommended adopting a Full Fuel Cycle (''FFC'') energy label for household appliances. This label's disclosure would include estimates of the energy used in transportation, distribution, generation, production, and extraction. The Group argued such a label would be consistent with the agency's mission to providing consumers complete and accurate information under the law. They further argued including such information would promote fuel neutrality and advance policy priorities by helping to tackle climate change. Finally, the commenters contended this labeling is now feasible because the FFC test procedures necessary to adopt this new label are straightforward and already available to the FTC from DOE.[92]

The Group further recommended streamlining the existing label to consist of the headlines ''RESIDENTIAL ENERGY COST & EMISSIONS'' and ''ENERGYGUIDE'' above a QR code, which would link consumers to the energy efficiency and associated FFC cost of products where data is available.

Discussion: The Commission does not propose amending the label to convert it into a QR code linking consumers to FFC information as suggested by some commenters. As discussed elsewhere in this Notice, replacing the current label with a QR code is likely to decrease the label's utility for consumers (*see* Sections V.F and VI *supra*).

[87] Labels are already widely available through retail and manufacturer websites as well as DOE's website as required by the Rule.

[88] Earthjustice argued that replacing physical labels with QR codes would be inconsistent with EPCA. We do not see the need to address that issue at this time. However, to the extent manufacturers want to communicate additional information to consumers, they may do so by providing other point-of-sale material, including QR codes, separate from the physical label.

[89] 76 FR 1038, 1044–45 (Jan. 6, 2011).

[90] 72 FR 49948, 49956 (Aug. 29, 2007).

[91] In addition, an anonymous commenter (#0013), citing research about the use of ozone-depleting hydrochlorofluorocarbons (''HCFCs'') in some refrigeration products, suggested that any refrigeration products containing HCFCs should contain labels informing consumers of such, or at least how to appropriately dispose of these items. The Commission does not propose to include this information on the label as it pertains to issues related to the end of the product's life and would likely crowd the information already there, thus potentially reducing the label's effectiveness.

[92] The Group also argued the FTC has legal authority to adopt FFC labels, noting that pursuant to 42 U.S.C. 6294(c)(1)(A), the contents of the label are at the discretion of the FTC so long as it accords with test procedures set forth by DOE under 42 U.S.C. 6293.26. Furthermore, EPCA expressly grants the FTC the ability to disclose additional information about energy consumption on labels if such information would assist consumers in making purchasing decisions.

In addition, the Commission does not propose amending existing labels to add FFC or GHG emissions information about individual products.[93] It is not clear, for instance, whether such additional technical information is helpful or whether the information already on the label (*e.g.,* the annual fuel costs), provides an adequate proxy for relative comparisons of the FFC impacts of competing products. Additionally, as the electricity grid evolves toward renewables and away from sources such as coal, the difference in emissions between fuels may narrow; thus diluting the relevance of such fuel comparisons. Further, additional FFC or GHG emissions information would clutter the label, potentially confusing consumers, and otherwise detract from the central disclosures related to the energy cost or energy efficiency of the labeled product. Accordingly, weighing the uncertain benefits of such a disclosure against the likely reduction in the label's utility, the Commission declines to propose these changes.

As an alternative, the Commission could explore, with DOE, creating online consumer resources to provide FFC and/or GHG information for individual covered products, even if such information is not included on the EnergyGuide labels. However, before committing resources to such a combined agency effort, the Commission invites comment on such an approach.

VIII. Additional Issues

Commenters also raised proposals and questions about a range of additional issues including lamp reporting, potential lamp and ceiling fan labels, transitional label language, range updates, compliance dates for ranges, television data updates, a categorical ranking system, bilingual information, coordination with other agencies, prescriptive requirements, and online label requirements. The following section summarizes these comments and provides the Commission's analysis.

A. Lamp Reporting

Background and Comments: The Commission sought comment in the ANPR on whether the Rule should require lamp manufacturers to include information regarding their Lighting Facts labels with their DOE data reports. The Rule already requires manufacturers of other covered consumer products to provide a website address linking to their EnergyGuide labels as part of their required data reports, which manufacturers submit through the DOE reporting system.[94] The Commission did not extend this requirement to the Lighting Facts labels in 2016 given appropriation restrictions placed on DOE spending related to light bulbs at that time. Instead, the Commission stated it would revisit the issue at ''a later date should circumstances warrant.'' [95]

In response, NEMA urged the Commission to refrain from requiring links to Lighting Facts labels in reports submitted via the DOE data website (CCMS) because current realities of the consumer marketplace do not warrant it. According to NEMA, the ''logistical coordination of the digital location of online content over time is very complicated for lamp products.'' In addition, because the label already contains the product characteristics, additional DOE reporting would only provide duplicative information. NEMA also argued the proposal would increase the burden on the FTC to review this data, much of which has little relevance to consumers.

Discussion: The Commission does not propose requiring lamp manufacturers to include information regarding their Lighting Facts labels with their data reports. Commenters did not identify any specific need or benefit from requiring this information in DOE reports. The Commission can revisit this issue if developments suggest a need.

B. Transitional Label Language

Background: The Commission sought comment on whether to phase out language on refrigerator and clothes washer labels added in 2013 to help distinguish models tested with the current DOE procedure from those rated with an older version.[96] This language, which advises consumers to ''Compare ONLY to other labels with yellow numbers,'' appears to now be obsolete and crowds the label with irrelevant information.

Comments: Commenters supported an eventual shift to the original label but recommended the Commission wait to do so until DOE completes certain changes to its requirements for the affected products. Specifically, AHAM suggested delaying revisions to the ''transitional'' labels until a new DOE test procedure provides an appropriate time to allow a return to the ''normal'' label in a single step. In its view, removing the current transitional language before such a test change could confuse consumers, burden manufacturers, and create complications should any new test procedures warrant similar transitional language.

Whirlpool agreed, stating it was unaware of any consumer complaints or confusion about the current label. It added upcoming changes to the DOE clothes washer test procedure are likely to be significant and thus may provide a logical time to transition to the conventional label. However, since the expected changes to the refrigerator/freezer test procedures are not as complex, Whirlpool recommended any such transition coincide with the amended energy conservation standards to minimize additional manufacturer burden. Finally, Electrolux generally supported reverting to the original format if manufacturer burdens are minimized in doing so.

Discussion: To minimize confusion resulting from a label change, the Commission does not propose amending the ''transitional'' label language for refrigerators and clothes washers at this time. However, it will consider doing so when future DOE test procedures or standards amendments provide an appropriate time to revert to the original label language.

C. Range Updates

Range and Cost Updates: A few commenters recommended the Commission update range and cost information more frequently. For example, NYSERDA urged the FTC to update the cost as often as feasible to increase accuracy. It also argued labels conveying estimated yearly energy costs calculated with a national average price from a fixed point in time are unlikely to accurately reflect regional consumer experience. It explained New York consumers, for example, living in a higher cost energy market, would find such labels less accurate than consumers in other parts of the country. In addition, Earthjustice stated the FTC should not permit outdated range information to persist on labels.

Discussion: The Commission does not propose changing the frequency of range and cost updates to labels. Although updates provide consumers with a useful estimate of a product's annual energy costs, ranges continue to provide a useful ''apples-to-apples'' comparison across products even as rates change. Moreover, range changes come with a downside. Specifically, they can lead to consumer confusion because they often result in showrooms displaying similar

[93] Under EPCA, the Commission may include on the label additional information relating to energy consumption if it would assist consumers in purchasing decisions or product use, and would not be unduly burdensome to manufacturers. 42 U.S.C. 6294(c)(5).

[94] 81 FR 63634 (Sept. 15, 2016); 16 CFR 305.11 (FTC reporting requirements).

[95] 81 FR at 63636.

[96] 78 FR 43974 (July 23, 2013).

models with the updated labels on newer units and outdated labels on the older ones. Increasing the frequency of updates only exacerbates this confusion. The Rule's current approach (the five-year update schedule first established in 2007) [97] strikes a reasonable balance between providing consumers updated information and minimizing the problems associated with frequent changes.

Likewise, the Commission does not propose changing the national cost estimates on the label to provide more granular information. The label's annual cost disclosure provides an estimate to allow consumers to compare the energy consumption of competing products quickly and effectively. Adding information degrades the use and utility of the label by making it harder to use and understand. The label already addresses this issue by stating it only provides an estimate.

D. Compliance Dates for Ranges

Background and Comments: Commenters also discussed the compliance period for future label updates. The current Rule requires manufacturers to implement range and cost changes within 90 days after issuance of updates (see § 305.12).[98] Whirlpool recommended expanding this period to 180 days for minor updates, such as range changes, because the manufacturing process for updating EnergyGuide labels generally takes four months. Specifically, according to Whirlpool, such updates involve hundreds of different part numbers in production at multiple locations, and therefore, draw resources away from other regulatory compliance efforts (*e.g.,* retesting and recertification to a new DOE or ENERGY STAR requirement). In its view, an extension to 180 days provides the necessary time to ''appropriately transition labels, without pulling away resources from other critical energy compliance projects'' with no harm to consumers. Finally, for any mandatory label changes, BWC asked the FTC to ''be sensitive to the timing of ongoing DOE rulemakings to minimize burdens on manufacturers.''

Discussion: In response to comments, the Commission proposes extending the transition period for label range and cost updates under § 305.12 to 180 days. As Whirlpool explained, manufacturer and supply chain issues have become increasingly complex. For routine label updates implemented every five years, the additional transition time is short relative to this schedule and should have little impact on consumers. The Commission seeks comment on this proposal, including whether and how it would affect consumers.

E. Updating the Television Test Data Requirements

The Commission also proposes a minor, conforming update to the television reporting requirements to match the recent DOE test procedure for those products.[99] Specifically, the proposed Rule would amend § 305.11(a)(3) to require reporting the following data for televisions: brand name, model number, screen size, on-mode power consumption, standby mode power consumption, dynamic luminance, and annual energy consumption. This proposal would ensure manufacturers submit data that matches the metrics yielded by the new test procedure rather than obsolete data.

F. Light Bulb and Ceiling Fan Labels

Background and Discussion: In the ANPR, the Commission sought comment on updating the electricity cost disclosure on the Lighting Facts and ceiling fan labels to reflect recent DOE national estimates. Commenters provided differing views on such changes. Earthjustice, for example, generally recommended updates for these products to avoid misleading consumers with outdated information. In contrast, NEMA, an association representing lighting manufacturers, recommended against changing the electricity cost information underlying the Lighting Facts because of the potential confusion resulting from a change. In addition, NEMA noted that because of the nature of the sales process and supply chain for lighting products, it would be ''impossible to assure all comparable product packaging reflects an updated electricity cost disclosure.'' Thus, in NEMA's view, such a change would create misleading inconsistencies among competing products as the label transition occurs.

The American Lighting Association (''ALA'') also opposed a change, for lighting as well as ceiling fans, noting it would create significant burdens for manufacturers. If the FTC chooses to update the light bulb labels, ALA urged allowing a rolling change over 36-months, which would be consistent with other Federal agencies and would give manufacturers the lead time necessary to make package changes. Similarly, Madison IAQ did not recommend the Commission change the ceiling fan labels. Should the Commission make changes, BAF, without explanation, recommended ''replacing the weighted average airflow and power numbers with airflow at high speed and power at high speed.'' In addition, Madison IAQ recommended renaming Airflow Efficiency to Average Airflow Efficiency since it is an average value.

Discussion: As discussed below, the Commission does not propose changes to lighting labels at this time. On balance, the problems associated with changing the vast array of light bulb packages on the market, including potential consumer confusion during the transition and the burdens of such a change, likely outweigh the benefits associated with updated cost numbers. The Lighting Facts label primarily benefits consumers by helping them compare the relative energy costs of similar models, not by providing their actual energy costs. The current label will continue to provide this benefit without changes. In addition, given the relatively low energy cost of most light bulbs and small energy cost difference, the benefits to individual consumers from updating the cost figure are likely to be lower than with other products. However, the Commission will continue to monitor changes in average electricity costs and will consider whether to provide future updates to these labels. Should the Commission require a new cost figure, it will consider providing manufacturers an adequate compliance period given the burdens involved with changing the large number of different lighting packages.

The Commission, however, proposes to require updating the energy cost information, as well as the range information, for ceiling fans by including them in the regular five-year schedule for label costs and range updates in § 305.12. Unlike the Lighting Facts label, ceiling fan labels contain a range of comparability, thus making regular updates to the label information likely more useful to consumers. Further, there are generally fewer ceiling fan products on the market compared to lamps, making the burden for label changes likely lower. Although ceiling fan labels feature energy cost and comparability range information as required by EPCA, the Rule currently does not specify an update schedule for that information. Accordingly, the proposal would include ceiling fans in the Rule's routine 5-year update schedule for the range and cost information to ensure regular range updates for those products. Consistent with other products bearing labels on packages, the Commission will seek to

[97] 72 FR 49948, 49959 (Aug. 29, 2007).

[98] EPCA sets this period for implementing range and cost changes to 60 days, unless the Commission provides for a later date. 42 U.S.C. 6296(c).

[99] 88 FR 16082 (Mar. 5, 2023).

set compliance dates for the next scheduled update in 2027 to minimize disruption to manufacturers' normal production schedules. Finally, the Commission does not propose changing the content of the label because commenters have not provided evidence of the need for such changes.

G. Categorical Ranking System

NYSERDA suggested the Commission consider categorical rankings on the label (for example ''good,'' ''better,'' ''best'') to bring ''a more holistic energy efficiency perspective, especially for product categories that do not already have an ENERGY STAR marking.'' In 2007, the Commission considered such a rating system after conducting consumer research. That research demonstrated the operating cost design performs well on objective tasks (*e.g.,* ranking by energy use), and the research participants identified the design as the most useful method for communicating energy information. Thus, the Commission rejected a categorical disclosure.[100] The record provides no compelling reason to revisit this decision.

H. Bilingual Information

Background: Under the current Rule, manufacturers may provide bilingual information in the form of an additional label or in separate point-of-purchase materials. However, the Rule only provides guidance on providing bilingual information, including guidance on content and format of bilingual labels, to manufacturers of lighting products.[101] The ANPR sought input on whether the Rule should offer similar guidance for other products and whether other improvements are warranted to help non-English speaking consumers with their purchasing decisions.

Comments: A few commenters offered suggestions. For example, NYSERDA urged the FTC to provide bilingual guidance across product categories to help manufacturers prepare information in multiple languages to communicate with a broader set of consumers. It also suggested that the FTC help encourage multiple language labeling through guidance on the use of a QR code or similar mechanism to allow consumers faced with paper labels in English to access information in their preferred languages. In contrast, Rheem, which already prepares Spanish and French versions of product literature, expressed concerns that any bilingual requirements ''will become overly burdensome and misdirected.'' It recommended the FTC leave decisions about such literature to the manufacturer's discretion.

Discussion: The Commission does not propose changing existing Rule provisions related to bilingual labels because it lacks evidence specific label content amendments (*e.g.,* a dedicated QR code) are necessary to help manufacturers and retailers communicate information to non-English speakers. Commenters have not provided any evidence non-English speakers find it impractical to use the labels' key disclosures, which are primarily numeric (*e.g.,* annual energy cost in dollars), to compare products. However, consistent with the comments, the FTC staff will explore creating additional guidance to better convey the label's information to non-English speakers. The Commission invites commenters to address what guidance would be helpful to consumers, manufacturers, and retailers. Additionally, the Commission seeks comment on whether and how mobile translation applications may help consumers understand labels.

I. Coordination With Other Agencies

Background and Comments: Several commenters urged the Commission to coordinate future label changes with Canadian regulators and the FTC's sister agencies. NEMA, for example, raised concerns that a recent Natural Resources Canada (''NRCan'') proposal conflicted with the FTC's Lighting Facts labeling requirements, and therefore, could cause confusion in the North American marketplace.[102] NEMA suggested coordination between the FTC and NRCan might reduce consumer confusion and avoid prohibitive financial burdens and the potential environmental costs of changing packaging. AHAM and Whirlpool also urged the FTC to harmonize activities with NRCan because ''changes to one label impact[s] the other.'' According to Whirlpool, the need for cooperation with Canada is paramount because the U.S. and Canadian markets often comprise an integrated supply chain. In its view, misalignment in labeling location, format, content, and timing can pose significant burdens for manufacturers and cause confusion for retailers and consumers. Given these realities, Whirlpool noted manufacturers generally use a side-by-side U.S. and Canada energy label, or a front-to-back configuration.

Commenters also urged the FTC to increase its coordination with DOE and EPA. For example, Whirlpool recommended the FTC ''make every attempt to align the compliance dates of any EnergyGuide label amendments'' with changes to DOE test procedures and efficiency standards, and EPA ENERGY STAR program requirements. Specifically, Whirlpool urged the FTC to wait to implement significant changes to the EnergyGuide labels until the compliance dates for the amended energy conservation and ENERGY STAR requirements.

Discussion: The Commission agrees cooperation with other Federal, State, and international agencies is important for ensuring consistency in labeling requirements where appropriate. The FTC staff will continue to communicate and coordinate with DOE, NRCan, and other appropriate agencies on issues relevant to the FTC labeling rules. The Commission also encourages industry members and other interested parties to alert FTC staff to any relevant developments involving such agencies.

J. Prescriptive Requirements

Background: In the ANPR, the Commission sought comments on any prescriptive requirements (*e.g.,* type size and style, label size, number of picas, paper weight, and label attachment provisions) in the Rule that are unnecessarily burdensome.

Comments: Commenters provided several suggestions to eliminate unnecessarily prescriptive requirements. Daiken, for example, recommended several specific label changes. First, for trim size dimensions under § 305.20(a), it recommended the FTC specify only minimum dimensions rather than a range of widths and lengths, and specify whole number minimums (*e.g.,* 7 inches for the length as opposed to 7 ⅜ inches). Second, it recommended allowing smaller labels for some products. Third, it recommended eliminating provisions in § 305.20(a) related to picas, centering, and depth, as well as requirements about type style and setting in § 305.20(b) because, in its view, they do not benefit consumers. Finally, Daiken argued the Commission should eliminate the paper stock weight and adhesive application rates requirements in § 305.20(d) because they are unnecessarily prescriptive. Crown, a boiler manufacturer, agreed, stating that ''label weight and material are irrelevant

[100] 72 FR 49948 (Aug. 29, 2007).

[101] 16 CFR 305.23(b)(6) and 16 CFR 305.23(c)(4) (label information may be presented in a second language either by using separate labels for each language or in a bilingual label with the English text in the format required by this section immediately followed by the text in the second language).

[102] *https://www.nrcan.gc.ca/energy-efficiency/energy-efficiency-regulations/general-service-lamps/24407.*

as long as the existing durability requirements are met.'' [103]

Discussion: The Commission proposes eliminating several prescriptive requirements that likely serve little purpose because they are either obsolete or already addressed by other Rule provisions. Specifically, the proposed amendments eliminate requirements related to picas, depth, specific paper weights, and position (*see, e.g.,* § 305.13).

These requirements provide little benefit beyond those already provided by other provisions in the Rule. For example, under this proposal, the Rule would continue to require a uniform appearance (fonts, font sizes, text placement, etc.) to ensure consumers recognize the label and are able to easily use it to make comparisons. For labels affixed to products, the proposal continues to require the adhesion capacity and paper stock be sufficient to prevent their dislodgment during normal handling throughout the chain of distribution to the retailer or consumer. These provisions should continue to ensure labels are uniform and sufficiently durable to remain on covered products.

K. Online Label Requirements

Background and Comments: The California IOUs suggested the FTC consider providing additional guidance for retailers regarding the online placement of display labels, particularly regarding their proximity to other product information. The current Rule requires disclosures to ''appear clearly and conspicuously and in close proximity to the covered product's price.'' [104] California IOUs asserted the ''close proximity'' language is ambiguous. They observed online retailers display the EnergyGuide information in a way that requires consumers to manually expand the supplemental section to view the link to the label. Therefore, they recommended the FTC ''guide online retailers to display the EnergyGuide label as the second in the series of product images to increase its prominence.'' [105]

Discussion: In response to these comments, the Commission proposes to amend the online label requirements to state that manufacturers posting the label or label link online in ''close proximity'' to the price must ensure that label or link itself is readily and immediately visible to the consumer. Further, the Commission proposes adding language to § 305.27 clarifying that, if an online seller uses an expandable image of the label (*e.g.,* ''thumbnail'' photographs in a series of product-related images) or clickable icon to comply with the Rule, that image or icon must be visible to the consumer without any additional scrolling, clicking, or other similar actions. These requirements should ensure online sellers cannot hide the EnergyGuide label in a long series of product photographs without imposing prescriptive requirements that could stifle innovation as online sales platforms continue to evolve.

IX. Paperwork Reduction Act

The current Rule contains recordkeeping, disclosure, testing, and reporting requirements that constitute information collection requirements as defined by the Paperwork Reduction Act (''PRA'').[106] Under the PRA, an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement, unless it displays a currently valid Office of Management and Budget (''OMB'') control number. OMB has approved the Rule's existing information collection requirements through February 29, 2024 (OMB Control No. 3084–0069).

The proposed amendments include new labeling requirements for air cleaners, clothes dryers, miscellaneous refrigerator products, and portable electric spas (collectively referred below as ''new labeled products'') that constitute information collections under the PRA. The proposed amendments also contain requirements which reduce the manufacturers' burden associated with labeling certain appliances and increase the burden for retailers by requiring them to ensure displayed products bear labels. Accordingly, the Commission is seeking OMB clearance specific to the Rule amendments.[107]

Burden estimates below are based on Census data, DOE figures and estimates, public comments, the agency's general knowledge of manufacturing practices, and trade association advice and figures. FTC staff estimates that there are 100 manufacturers producing 5,000 basic models (*i.e.,* units with essentially identical physical and electrical characteristics) of the proposed new products (air cleaners—700; clothes dryers—1,700; miscellaneous refrigeration products—1,100; portable electric spas—1,500).

Reporting: The Rule requires manufacturers of covered products to annually submit a report for each current model containing the same information that must be submitted to the DOE pursuant to 10 CFR part 429. In lieu of submitting the required information to the Commission, manufacturers may submit such information to DOE directly via the agency's Compliance Certification Management System, available at *https://regulations.doe.gov/ccms,* as provided by 10 CFR 429.12. Because manufacturers are already required to submit these reports to DOE, FTC staff estimates any additional burden associated with providing the information to the FTC is minimal. FTC staff estimates the average reporting burden for manufacturers of the proposed new products will be approximately 15 hours per manufacturer. Based on this estimate, the annual reporting burden for manufacturers of new labeled products is 1,500 hours (15 hours × 100 manufacturers). Staff estimates that information processing staff, at an hourly rate of $18.97,[108] will typically perform the required tasks, for an estimated annual labor cost of $28,455.

Manufacturer Labeling: The amendments require that manufacturers create labels for the four new labeled product categories. Since EPCA and the Rule specify the content and format for the required labels, and FTC staff provide online label templates, manufacturers need only input the energy consumption figures and other product-specific information derived from testing. FTC staff estimates the time to incorporate the required information into labels and label-covered products is five hours per basic model. Accordingly, staff estimates the approximate annual burden involved in creating labels for covered products is

[103] *See also* The Marley Company comments.

[104] 16 CFR 305.27.

[105] Other commenters shared experiences indicating they may benefit from clarifying the ''close proximity'' requirement for online labels. One commenter (Ring) stated they rely on online research to narrow their choices before visiting stores. Another (DuSaint) stated he found online comparison shopping for appliances to be generally helpful, other than in situations where appliances require immediate replacement through a visit to a physical store. Merriam also argued the energy labels ''should be clearly and consistently included in product pictures for online retailers'' but did not specify any changes to the existing online ''catalog'' requirements in the Rule.

[106] 44 U.S.C. 3501 *et seq.; see also* 5 CFR 1320.3(c).

[107] The PRA analysis for this rulemaking focuses strictly on the information collection requirements created by and/or otherwise affected by the amendments. Unaffected information collection provisions have previously been accounted for in past FTC analyses under the Rule and are covered by the current PRA clearance from OMB.

[108] These labor cost estimates are derived from the Bureau of Labor Statistics (''BLS'') figures in ''Table 1. National employment and wage data from the Occupational Employment and Wage Statistics survey by occupation, May 2022,'' available at: *https://www.bls.gov/news.release/ocwage.t01.htm.*

25,000 hours [5,000 basic models × 5 hours]. Staff estimates that information processing staff, at an hourly rate of $18.97,[109] will typically perform the required tasks, for an estimated annual labor cost of $474,250.

The proposed Rule would also require manufacturers to affix labels to shipped clothes dryers, miscellaneous refrigeration products (''MREFs''), and portable electric spas (estimates include MREFs at 3,000,000; dryers at 8,000,000).[110] For dryers and MREFs (11,000,000 units), the burden would only apply to units designated as showroom models, which FTC estimates will account for about 0.2% of shipped models. Consistent with past estimates, the FTC estimates it takes 4 seconds for a manufacturer to affix a label for showroom display. Accordingly, staff estimates the burden for affixing labels on these new products will be 24 hours (22,000 units × 4 seconds). Staff estimates that information processing staff, at an hourly rate of $18.97, will typically perform the required tasks, for an estimated annual labor cost of $455.

In addition, the proposal would relax label attachment requirements for refrigerators and freezers, dishwashers, and clothes washers by allowing manufacturers to ship an unaffixed label with most units (about 24 million units). The FTC estimates the reduction in burden from this proposed change to be 26,667 hours (24,000,000 × 4 seconds).

Thus, the estimated burden on manufacturers from the proposed amendments would be a net reduction of 143 hours ([1,500 (reporting) + 25,000 (labeling) + 24 (affixing labels)] − 26,667]).

Retailer Showroom Labeling: The proposed Rule would require retailers to ensure that refrigerator products, dishwashers, clothes washers, and clothes dryers displayed in showrooms bear a label. FTC staff estimates there are about 14,000 showroom appliance stores in the U.S. and that stores on average display about 50 labeled products per year. Out of these, the FTC estimates 20% of those showroom models will require retailers to locate the label in the box and affix it to a product, which will take about five minutes per display model. Most showroom units will already be labeled by manufacturers and thus require no action by the retailer. Accordingly, the estimated total burden is 11,667 hours (50 units × .20 × 14,000 × 5 minutes). Staff estimates that retail sales staff, at an hourly rate of $15.62,[111] will typically perform the required tasks, for an estimated annual labor cost of $182,239.

Testing: Manufacturers of the new labeled products must test each basic model they produce to determine energy usage, but the majority of tests conducted are required by DOE rules. As a result, it is likely only a small portion of the tests conducted are attributable to the Rule's requirements. In addition, manufacturers need not subject each basic model to testing annually; they must retest only if the product design changes in such a way as to affect energy consumption. FTC staff estimates that 25% of all basic models are tested annually because of the Rule's requirements. Accordingly, the estimated annual testing burden for new labeled products is 15,400 hours.[112] Staff estimates that engineering technicians, at an hourly rate of $30.95, will typically perform the required tasks, for an estimated annual labor cost of $476,630.

Online Label Posting: The proposal would require manufacturers to post images of their EnergyGuide labels online for the new labeled products. Staff estimates the burden associated with this requirement based on the number of models of covered products. Given approximately 5,000 total models at an estimated five minutes per model, staff estimates that this requirement entails a burden of 417 hours (5,000 basic models × 5 minutes). Staff estimates that information processing staff, at an hourly rate of $18.97,[113] will typically perform the required tasks, for an estimated annual labor cost of $7,910.

Recordkeeping: The Rule also requires manufacturers of covered products to retain records of test data generated in performing the tests to derive information included on labels.[114] The FTC estimates the annual recordkeeping burden for manufacturers of new labeled products will be approximately one minute per basic model to store relevant data. Accordingly, the estimated annual recordkeeping burden would be approximately 83 hours (5,000 basic models × one minute). Staff estimates that information processing staff, at an hourly rate of $18.97, will typically perform the required tasks, for an estimated annual labor cost of $1,575.

Online and Retail Catalog Disclosures: Staff estimates there are approximately 400 sellers of new labeled product categories who are subject to the Rule's catalog disclosure requirements. Staff has previously estimated covered online and catalog sellers spend approximately 17 hours per year to incorporate relevant product data for products that are currently covered by the Rule. Staff estimates the requirements for new labeled product categories will add an additional 4 hours per year in incremental burden per seller. Staff estimates these additions will result in an incremental burden of 1,600 hours (400 sellers × 4 hours annually). Staff estimates that information processing staff, at an hourly rate of $18.97,[115] will typically perform the required tasks, for an estimated incremental annual labor cost of $30,352.

Estimated annual non-labor cost burden: Staff anticipates that manufacturers are not likely to require any significant capital costs to comply with the amendments.

X. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA'') [116] requires that the Commission conduct an analysis of the anticipated economic impact of the proposed amendment on small entities. The RFA requires that the Commission provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a proposed rule, and a Final Regulatory Flexibility Analysis (''FRFA'') with a final rule, if any, unless the Commission certifies that the rule will not have a significant economic impact on a substantial number of small entities.[117] While the Commission recognizes that some of the affected manufacturers and retailers may qualify as small businesses under the relevant thresholds as determined by the Small Business Administration, it does not anticipate a substantial number of these small entities will face a significant burden under the proposed

[109] *Id.*

[110] As discussed in this Notice, the Commission has not proposed a specific labeling method for portable electric spas and is seeking comment on that issue. The estimate here assumes spa labels will appear on packaging and thus will not create the type of incremental burden posed by labels affixed separately to the product (*e.g.,* labels for appliances such as refrigerators). Staff estimates annual shipments of these products are about 500,000. Should labeling for these products be finalized and impose a different burden, estimates will be updated depending on the final labeling method.

[111] BLS, *supra* n.108.

[112] The FTC has applied different test hour burdens depending on the product: air cleaners—700 basic models × 0.25 × 40 hours = 7,000 hours; clothes dryers—1,700 basic models × 0.25 × 4 hours = 1,700 hours; portable electric spas—1500 basic models × 0.25 × 12 hours = 4,500 hours; MREFs—1,100 basic models × 0.25 × 8 hours = 2,200 hours.

[113] BLS, *supra* n.108.

[114] *See* 16 CFR 305.28.

[115] BLS, *supra* n.108.

[116] 5 U.S.C. 601–612.

[117] 5 U.S.C. 605. The proposed conforming changes to central air conditioner descriptors will have no impact on the Rule's current burden.

rule. Therefore, based on available information, the Commission certifies that amending the Rules as proposed will not have a significant economic impact on a substantial number of small businesses.

The Commission estimates the amendments will apply to 400 online and paper catalog sellers of covered products, about 100 product manufacturers, and approximately 14,000 retail appliance stores. The Commission expects that approximately 5,150 of these various entities qualify as small businesses (5,000 of which are appliance stores). More details about these small entities can be found under section C below.

Accordingly, this document serves as notice to the Small Business Administration of the FTC's certification of no effect. To ensure the accuracy of this certification, however, the Commission requests comment on whether the proposed rule will have a significant impact on a substantial number of small entities, including specific information on the number of entities that would be covered by the proposed rule, the number of these companies that are small entities, and the average annual burden for each entity. Although the Commission concludes under the RFA that the proposed amendments to the Rule in this notice would not, if promulgated, have a significant impact on the affected small entities, the Commission has determined, nonetheless, that it is appropriate to publish an IRFA in order to inquire into the impact of the proposed rule on small entities. Therefore, the Commission has prepared the following analysis:

A. Description of the Reasons That Action by the Agency Is Being Taken

As explained in more detail above, the Commission is proposing expanded product coverage and additional improvements to the Rule to help consumers in their purchasing decisions of consumer products.

B. Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The objective of the proposed Rule is to improve the effectiveness of the current labeling program by providing energy information for additional product categories and improving existing labels. The legal basis for the Rule is the Energy Policy and Conservation Act (42 U.S.C. 6292 *et seq.*).

C. Small Entities to Which the Proposed Rule Will Apply

Under the Small Business Size Standards issued by the Small Business Administration, appliance manufacturers qualify as small businesses if they have fewer than 1,500 employees. Catalog sellers qualify as small businesses (miscellaneous retailers) if their sales are less than $11.5 million annually. Retail appliances firms qualify if their annual receipts are $40 million or less. The Commission estimates that there are approximately 150 online sellers and 5,000 appliance retailers that are both subject to the proposed Rule's requirements and qualify as small businesses.[118] The Commission seeks comment and information regarding the estimated number and nature of small business entities for which the proposed Rule would have a significant economic impact.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The changes under consideration would increase reporting or recordkeeping requirements associated with the new labeled products proposed in this Notice (*i.e.,* air cleaners, clothes dryers, miscellaneous refrigerator products, and portable electric spas). The amendments also contain compliance requirements for appliance retailers to ensure that units placed on showroom floors have labels. More details on these reporting, disclosure and recordkeeping requirements can be found under (IX) Paperwork Reduction Act.

E. Duplicative, Overlapping, or Conflicting Federal Rules

The Commission has not identified any other Federal statutes, rules, or policies that duplicate, overlap, or conflict with the proposed Rule. During this proceeding, FTC staff has consulted with DOE staff and other agencies on the issues addressed in this Notice. The Commission invites comment and information on this issue.

F. Significant Alternatives to the Proposed Rule

The Commission seeks comment and information on the need, if any, for alternative compliance methods that, consistent with the statutory requirements, would reduce the economic impact of the Rule on small entities. The Commission has already taken steps to reduce the economic impact of the Rule in this NPRM. The Commission considered but did not adopt a proposal to impose an additional requirement for manufacturers to include IMEF information on labels for clothes washers. The Commission also solicited comments on alternatives to the current ''showroom-ready'' approach for affixing labels. Further, in proposing new requirements, the Commission considered ways to minimize retailer burden, including providing flexibility for label materials and attachment methods, requiring manufacturers to ship labels in a ''showroom ready'' state for designated floor models, allowing retailers to use existing electronic labels accessed through DOE's website, and ensuring retailers have adequate time to comply with any new requirements. The Commission considered electronic labeling. The Commission is also seeking comment on how with DOE, the agencies might create online consumer resources to provide FFC and/or GHG information for individual covered products, in lieu of requiring such information on the EnergyGuide labels. The Commission is currently unaware of the need to adopt any special provisions for small entities. However, if such issues are identified, the Commission could consider alternative approaches such as extending the effective date of these amendments for online and retail sellers to allow them additional time to comply beyond the labeling deadline set for manufacturers. If the comments filed in response to this Notice identify small entities that are affected by the proposed Rule, as well as alternative methods of compliance that would reduce the economic impact of the Rule on such entities, the Commission will consider the feasibility of such alternatives and determine whether they should be incorporated into the final Rule.

[118] 81 FR 62681 (Sept. 12, 2016).

XI. Request for Comment

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before April 2, 2024. Write ''Energy Labeling Rule (16 CFR part 305) (Matter No. R611004)'' on your comment. Because of the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. As a result, we strongly encourage you to submit your comments online through the *https://www.regulations.gov* website. To ensure that the Commission considers your online comment, please follow the instructions on the web-based form. Your comment—including your name and your State—will be placed on the public record of this proceeding, including the *https://*

www.regulations.gov website. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on *https://www.regulations.gov.*

If you file your comment on paper, write ''Energy Labeling Rule (16 CFR part 305) (Matter No. R611004)'' on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H–144 (Annex L), Washington, DC 20580. If possible, submit your paper comment to the Commission by overnight service.

Because your comment will be placed on the publicly accessible website at *www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other State identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov,* we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this document and the news release describing it, and visit *https://www.regulations.gov/docket/FTC-2024-0008* to read a plain-language summary of the proposed rule. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before April 2, 2024. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Because written comments appear adequate to present the views of all interested parties, the Commission has not scheduled an opportunity for presentation of oral comments regarding these proposed amendments. Interested parties may request an opportunity to present oral data, views, and comments on the proposed amendments. If such a request is made, the Commission will publish a document in the **Federal Register** stating the time and place for such oral presentation(s) and describing the procedures that will be followed. Interested parties who wish to present oral views must submit a request, on or before March 18, 2024, in the form of a written comment that describes the issues on which the party wishes to speak. If no oral presentations are scheduled, the Commission will base its decision on the written rulemaking record.

XII. Communications by Outside Parties to the Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding, from any outside party to any Commissioner or Commissioner's advisor, will be placed on the public record. *See* 16 CFR 1.26(b)(5).

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

For the reasons set out above, the Commission proposes to amend 16 CFR part 305 as follows:

PART 305—ENERGY AND WATER USE LABELING FOR CONSUMER PRODUCTS UNDER THE ENERGY POLICY AND CONSERVATION ACT (''ENERGY LABELING RULE'')

■ 1. The authority citation for Part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

■ 2. Amend § 305.2 by redesignating paragraph (l)(24) as paragraph (l)(27), adding new paragraphs (l)(24), (l)(25), and (l)(26), and revising paragraph (p) to read as follows:

§ 305.2 Definitions.

* * * * *

(l) * * *

(24) Room air cleaners.

(25) Miscellaneous refrigeration products.

(26) Portable electric spas.

* * * * *

(p) *Energy efficiency rating* means the following product-specific energy usage descriptors: Annual fuel utilization efficiency (AFUE) for furnaces; combined energy efficiency ratio (CEER) for room and portable air conditioners; seasonal energy efficiency ratio 2 (SEER2) for the cooling function of central air conditioners and heat pumps; heating seasonal performance factor 2 (HSPF2) for the heating function of heat pumps; airflow efficiency for ceiling fans; combined energy factor (CEF) for clothes dryers; Integrated Energy Factor (''IEF'') for air cleaners; and, thermal efficiency (TE) for pool heaters, as these descriptors are determined in accordance with tests prescribed under section 323 of the Act (42 U.S.C. 6293). These product-specific energy usage descriptors shall be used in satisfying all the requirements of this part.

* * * * *

■ 3. Amend § 305.3 by adding paragraphs (k), (l), (m), and (n) to read as follows:

§ 305.3 Description of appliances and consumer electronics.

* * * * *

(k) *Room air cleaner* means an air cleaner that—

(1) Is a portable or wall mounted (fixed) unit, excluding ceiling mounted unit, that plugs into an electrical outlet;

(2) Operates with a fan for air circulation; and

(3) Contains means to remove, destroy, and/or deactivate particulates.

The term *portable* is as defined in section 2.1.3.1 of AHAM AC–7–2022, and the term *fixed* is as defined in section 2.1.3.2 of AHAM AC–7–2022.

(l) *Clothes dryer* means a cabinet-like appliance designed to dry fabrics in a

tumble-type drum with forced air circulation. The heat source is either gas or electricity, and the drum and blower(s) are driven by an electric motor(s).

(m) *Miscellaneous refrigeration product* means a consumer refrigeration product other than a refrigerator, refrigerator-freezer, or freezer, which includes coolers and combination cooler refrigeration products.

(n) *Portable electric spa* means a factory-built electric spa or hot tub, supplied with equipment for heating and circulating water at the time of sale or sold separately for subsequent attachment.

■ 4. Revise § 305.9 to read as follows:

§ 305.9 Duty to provide labels on websites and to retailers.

(a) For each covered product required by this part to bear an EnergyGuide or Lighting Facts label, the manufacturer must make a copy of the label available on a publicly accessible website in a manner that allows catalog sellers to hyperlink to the label or download it for use in websites or paper catalogs. The label for each specific model must remain on the website for six months after production of that model ceases.

(b) For refrigerators, refrigerator-freezers, miscellaneous refrigeration products, freezers, dishwashers, clothes washers, and clothes dryers, manufacturers must provide a copy of the label required by this part to a retailer upon request of that retailer, in a form requested by the retailer, such as physical or electronic.

■ 5. Amend § 305.10 by revising paragraph (h) and adding paragraphs (m), (n), (o), and (p) to read as follows:

§ 305.10 Determinations of capacity.

* * * * *

(h) *Furnaces (including boilers).* The capacity shall be the heating capacity in Btu's per hour, rounded to the nearest 1,000 Btu's per hour, as determined according to appendices N and EE to 10 CFR part 430, subpart B, as applicable.

* * * * *

(m) *Room air cleaners:* The capacity shall be the effective room size according to10 CFR parts 429 and 430, subpart B, with rounding determined in accordance with 10 CFR part 430.

(n) *Clothes dryers:* The capacity shall be the drum capacity as determined according to Department of Energy test procedures in 10 CFR part 430, subpart B, expressed in terms of ''Capacity (tub volume)'' in cubic feet, rounded to the nearest one-tenth of a cubic foot, and the capacity class designations ''standard'' or ''compact.''

(o) *Miscellaneous refrigeration product:* The capacity shall be the total refrigerated volume (VT) in cubic feet, rounded to the nearest one-tenth of a cubic foot, as determined according to appendix A to 10 CFR part 430, subpart B.

(p) *Portable Electric Spa:* The capacity shall be the fill volume, which means the volume of water held by the portable electric spa when it is filled as specified in appendix GG to 10 CFR part 430, subpart B.

■ 6. Amend § 305.11 by revising paragraphs (a)(3) and (b)(1) to read as follows:

§ 305.11 Submission of data.

(a) * * *

(3) Manufacturers of televisions shall submit annually a report containing the brand name; model number; screen size (diagonal in inches); on mode power consumption, standby mode power consumption; dynamic luminance; and annual energy consumption (kWh/year) for each basic model in current production. The report should also include a starting serial number, date code, or other means of identifying the date of manufacture with the first submission for each basic model. In lieu of submitting the required information to the Commission as required by this section, manufacturers may submit such information to the Department of Energy via the Compliance and Certification Management System (CCMS) at *https://regulations.doe.gov/ccms* as provided by 10 CFR 429.12.

* * * * *

(b)(1) All data required by paragraph (a) of this section except serial numbers shall be submitted to the Commission annually, on or before the following dates:

Product category	Deadline for data submission
Refrigerators	Aug. 1.
Refrigerators-freezers	Aug. 1.
Freezers	Aug. 1.
Miscellaneous refrigeration products	Aug. 1.
Central air conditioners	July 1.
Heat pumps	July 1.
Dishwashers	June 1.
Water heaters	May 1.
Room air conditioners	July 1.
Portable air conditioners	Feb. 1.
Room air cleaners	Dec. 1.
Furnaces	May 1.
Pool heaters	May 1.
Portable Electric Spas	TBD.
Clothes washers	Oct. 1.
Clothes dryers	Oct. 1.
Fluorescent lamp ballasts	Mar. 1.
Showerheads	Mar. 1.
Faucets	Mar. 1.
Water closets	Mar. 1.
Ceiling fans	Mar. 1.
Urinals	Mar. 1.
Metal halide lamp fixtures	Sept. 1.
General service fluorescent lamps	Mar. 1.
Medium base compact fluorescent lamps	Mar. 1.
General service incandescent lamps	Mar. 1.
Televisions	June 1.

* * * * *

■ 7. Amend § 305.12 by revising paragraphs (a) and (b) to read as follows:

§ 305.12 Ranges of comparability on the required labels.

(a) *Range of estimated annual energy costs or energy efficiency ratings.* The range of estimated annual operating costs or energy efficiency ratings for each covered product (except televisions, fluorescent lamp ballasts, lamps, metal halide lamp fixtures, showerheads, faucets, water closets, and urinals) shall be taken from the appropriate appendix to this part in effect at the time the labels are affixed to the product. The Commission shall publish revised ranges in the **Federal Register** in 2027. When the ranges are revised, all information disseminated after 180 days following the publication of the revision shall conform to the revised ranges. Products that have been labeled prior to the effective date of a modification under this section need not be relabeled.

(b) *Representative average unit energy cost.* The Representative Average Unit Energy Cost to be used on labels as required by §§ 305.14 through 305.19 and disclosures as required by § 305.27 are listed in appendices K1 and K2 to this part. The Commission shall publish revised Representative Average Unit Energy Cost figures in the **Federal Register** in 2027. When the cost figures are revised, all information disseminated after 180 days following the publication of the revision shall conform to the new cost figure.

* * * * *

■ 8. Revise § 305.13 to read as follows:

§ 305.13 Layout, format, and placement of labels for refrigerators, refrigerator-freezers, miscellaneous refrigeration products, freezers, dishwashers, clothes washers, clothes dryers, water heaters, room air conditioners, portable air conditioners, room air cleaners, portable electric spas, and pool heaters.

(a) *Coverage.* The requirements of this section apply to labels for refrigerators, refrigerator-freezers, freezers,

miscellaneous refrigeration products, dishwashers, clothes washers, clothes dryers, water heaters, room air conditioners, portable air conditioners, room air cleaners, portable electric spas, and pool heaters.

(b) *Layout.* Energy labels shall use one size, similar colors, and typefaces with consistent positioning of headline, copy, and charts to maintain uniformity for immediate consumer recognition and readability. With the exception of instantaneous water heaters, trim size dimensions for the labels shall be as follows: Width must be between 5¼ inches and 5½ inches (13.34 cm. and 13.97 cm.); length must be between 7⅜ inches (18.73 cm.) and 7⅝ (19.37 cm.). Labels for instantaneous water heaters may be as small as a 3¾ inches (9.53 cm.) in width and 4⅞ inches (12.38 cm.) in length. All positioning, spacing, type sizes, and line widths should be similar to and consistent with the prototype and sample labels in appendix L to this part.

(c) *Type style and setting.* The Arial Narrow series typeface or equivalent shall be used exclusively on the label. Specific sizes and faces to be used are indicated on the prototype labels. No hyphenation should be used in setting headline or copy text. Positioning and spacing should follow the prototypes closely. See the prototype labels for specific directions.

(d) *Colors.* Except as indicated in paragraph (e)(3) of this section, the basic colors of all labels covered by this section shall be process yellow or equivalent and process black. The label shall be printed full bleed process yellow. All type and graphics shall be print process black.

(e) *Label types.* Except as indicated in paragraphs (e)(3) and (e)(4) of this section, the labels must be affixed to the product in the form of an adhesive label for any product covered by this section, or in the form of a hang tag for refrigerators, refrigerator-freezers, freezers, miscellaneous refrigerator products, dishwashers, clothes washers, and clothes dryers as follows:

(1) *Adhesive labels.* All adhesive labels should be applied so they can be easily removed without the use of tools or liquids, other than water. The adhesion capacity and paper stock should be sufficient to prevent their dislodgment during normal handling throughout the chain of distribution to the retailer or consumer. In lieu of a label with adhesive backing, manufacturers may adhere the label with adhesive tape, provided the tape is affixed along the entire top and bottom of the label.

(2) *Hang tags.* Labels may be affixed to the product interior in the form of a hang tag using cable ties or double strings connected through reinforced punch holes, or with attachment and label material of equivalent or greater strength and durability. If paper stock is used for hang tags, it shall have a basic weight sufficient to prevent dislodgment during normal handling throughout the chain of distribution to the retailer or consumer. When materials are used to attach the hang tags to appliance products, the materials shall be of sufficient strength to ensure that if gradual pressure is applied to the hang tag by pulling it away from where it is affixed to the product, the hang tag will tear before the material used to affix the hang tag to the product breaks.

(3) *Package labels for certain products.* Labels for electric and gas instantaneous water heaters shall be printed on or affixed to the product's packaging in a conspicuous location. Labels for room air conditioners, portable air conditioners, air cleaners, and portable electric spas shall be printed on or affixed to the principal display panel of the product's packaging. The labels for electric and gas instantaneous water heaters, room air conditioners, room air cleaners, and portable air conditioners shall be black type and graphics on a process yellow or other neutral contrasting background.

(4) *Non-Showroom Designated Appliances:* For refrigerators, refrigerator-freezers, freezers, miscellaneous refrigeration products, dishwashers, clothes washers, and clothes dryers not designated by manufacturers as showroom display units or otherwise shipped by manufacturers with point of purchase material intended for retail or showroom display, manufacturers may include the label with the unit consistent with the requirements of paragraph (f)(3) of this section. Such labels must be printed on paper stock but need not comply with the specific requirements of paragraphs (e)(1) and (e)(2) of this section.

(f) *Placement—*

(1) *Adhesive labels.* Manufacturers shall affix adhesive labels to the covered products in such a position that it is easily read by a consumer examining the product. The label should be generally located on the upper-right-front corner of the product's front exterior. However, some other prominent location may be used as long as the label will not become dislodged during normal handling throughout the chain of distribution to the retailer or consumer. The label can be displayed in the form of a flap tag adhered to the top of the appliance and bent (folded at 90°) to hang over the front, as long as this can be done with assurance that it will be readily visible.

(2) *Hang tags.* A hang tag shall be affixed to the interior of the product in such a position that it can be easily read by a consumer examining the product. A hang tag can be affixed in any position that meets this requirement as long as the label will not become dislodged during normal handling throughout the chain of distribution to the retailer or consumer. Hang tags may only be affixed in refrigerators, refrigerator-freezers, freezers, miscellaneous refrigerator products, dishwashers, clothes washers, and clothes dryers.

(3) *Non-Showroom-Designated Appliance Labels.* Labels for units covered by paragraph (e)(4) of this section must be shipped with the product in a location readily visible to retailers and consumers examining the contents of the product's packaging.

(g) *Retailer Responsibilities.* Retailers who choose to display any refrigerator, refrigerator-freezer, freezer, miscellaneous refrigerator product, dishwasher, clothes washer, and clothes dryer must ensure the model's EnergyGuide label is affixed to the product in a location easily visible to a consumer examining the product.

■ 9. Amend § 305.14 by revising the section heading and paragraph (a)(9)(iv) to read as follows:

§ 305.14 Label content for refrigerators, refrigerator-freezers, freezers, and miscellaneous refrigeration products.

(a) * * *

(9) * * *

(iv) Labels for freezers and miscellaneous refrigeration products must contain a statement as illustrated in the prototype labels in appendix L and specified as follows (fill in the blanks with the appropriate energy cost figure):

Your cost will depend on your utility rates and use.

[For freezers, insert statement required by paragraph (a)(10)(v) of this section. For miscellaneous refrigeration products, add the following statement: Cost range based on models of similar size capacity.].

Estimated energy cost based on a national average electricity cost of ____ cents per kWh.

ftc.gov/energy.

* * * * *

■ 10. Amend § 305.15 by revising the section heading and paragraph (a) to read as follows:

§ 305.15 Label content for clothes washers and clothes dryers.

(a) *Label content.*

(1) Headlines and texts, as illustrated in the prototype and sample labels in appendix L to this part, are standard for all labels.

(2) Name of manufacturer or private labeler shall, in the case of a corporation, be deemed to be satisfied only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used. Inclusion of the name of the manufacturer or private labeler is optional at the discretion of the manufacturer or private labeler.

(3) Model number(s) will be the designation given by the manufacturer or private labeler.

(4) Capacity or size is that determined in accordance with this part.

(5) Estimated annual operating costs are as determined in accordance with this part. Labels must disclose estimated annual operating cost for both electricity and/or natural gas as illustrated in the sample labels in appendix L to this part.

(6) Unless otherwise indicated in this paragraph, ranges of comparability for estimated annual operating costs are found in the appropriate appendices accompanying this part.

(7) Placement of the labeled product on the scale shall be proportionate to the lowest and highest estimated annual operating costs.

(8) Labels for clothes washers must contain the model's estimated annual energy consumption as determined in accordance with this part and as indicated on the sample labels in appendix L. Labels for clothes dryers must contain the model's combined energy factor (CEF) as determined in accordance with this part and as indicated on the sample labels in appendix L.

(9) The clothes washer label shall contain the text and graphics illustrated in the sample labels in appendix L, including the statement:

Compare ONLY to other labels with yellow numbers.

Labels with yellow numbers are based on the same test procedures.

(10) Labels for clothes washers must contain a statement as illustrated in the prototype labels in appendix L and specified as follows (fill in the blanks with the appropriate capacity and energy cost figures):

Your costs will depend on your utility rates and use.

Cost range based only on [compact/standard] capacity models.

Estimated energy cost is based on six wash loads a week and a national average electricity cost ____ of cents per kWh and natural gas cost of $ ____ per therm.

ftc.gov/energy.

(11) The clothes dryer label shall contain the text and graphics illustrated in the sample labels in appendix L, including a statement as illustrated in the prototype labels in appendix L and specified as follows (fill in the blanks with the appropriate capacity and energy cost figures):

Your costs will depend on your utility rates and use.

Cost range based only on [compact/standard] capacity models.

Estimated energy cost is based on five wash loads a week and a national average [electricity cost of ____ cents per kWh or natural gas cost of $ ____ per therm].

ftc.gov/energy.

(12) The following statement shall appear on each label as illustrated in the prototype and sample labels in appendix L:

Federal law prohibits removal of this label before consumer purchase.

* * * * *

■ 11. Amend § 305.18 by revising the section heading and paragraphs (a)(8) and (a)(9), redesignating paragraph (a)(10) as paragraph (a)(12), and adding new paragraphs (a)(10) and (a)(11) to read as follows:

§ 305.18 Label content for room air conditioners, portable air conditioners, and room air cleaners.

(a) * * *

(8) Labels for room air conditioners, portable air conditioners, and room air cleaners must contain the model's estimated annual energy consumption as determined in accordance with this part and as indicated on the sample labels in appendix L. Labels must contain the model's energy efficiency rating, as applicable, as determined in accordance with this part and as indicated on the sample labels in appendix L to this part.

(9) Labels for room air conditioners and portable air conditioners must contain a statement as illustrated in the prototype labels in appendix L of this part and specified as follows (fill in the blanks with the appropriate model type, year, energy type, and energy cost figure):

Your costs will depend on your utility rates and use.

Cost range based only on models [of similar capacity; of similar capacity without reverse cycle and with louvered sides; of similar capacity without reverse cycle and without louvered sides; with reverse cycle and with louvered sides; or with reverse cycle and without louvered sides].

Estimated annual energy cost is based on a national average electricity cost of ____ cents per kWh and a seasonal use of 8 hours use per day over a 3-month period.

For more information, visit *www.ftc.gov/energy.*

(10) Labels for air cleaners must contain the model's estimated annual energy consumption as determined in accordance with this part and as indicated on the sample labels in appendix L. Labels must also contain the model's independent energy factor and clean air delivery rate, as applicable, as determined in accordance with this part and displayed on the label consistent with the sample labels in appendix L to this part.

(11) Labels for air cleaners must contain a statement as illustrated in the prototype labels in appendix L of this part and specified as follows (fill in the blanks with the appropriate model type, year, energy type, and energy cost figure):

Your costs will depend on your utility rates and use.

Cost range based only on models of similar capacity.

The Clean Air Delivery Rate is based on the removal of particulate matter that is 2.5 micrometers wide or smaller ($PM_{2.5}$ CADR).

Estimated annual energy cost is based on 16 hours of operation per day and a national average electricity cost of ____ cents per kWh.

For more information, visit *www.ftc.gov/energy.*

(12) The following statement shall appear on each label as illustrated in the prototype and sample labels in appendix L:

Federal law prohibits removal of this label before consumer purchase.

* * * * *

■ 12. Amend § 305.19 by revising the section heading and paragraph (a) introductory text, redesignating paragraph (b) as paragraph (c), and adding new paragraph (b) to read as follows:

§ 305.19 Label content for pool heaters and portable electric spas.

(a) *Label content for pool heaters.*

* * * * *

(b) *Label content for electric spas.*

(1) Headlines and texts, as illustrated in the prototype and sample labels in appendix L to this part, are standard for all labels.

(2) Name of manufacturer or private labeler shall, in the case of a corporation, be deemed to be satisfied only by the actual corporate name,

which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used. Inclusion of the name of the manufacturer or private labeler is optional at the discretion of the manufacturer or private labeler.

(3) Model number(s) will be the designation given by the manufacturer or private labeler.

(4) Capacity or size is that determined in accordance with this part.

(5) Estimated annual heating costs are as determined in accordance with this part.

(6) Energy Used in watts is as determined in accordance with this part.

(7) Unless otherwise indicated in this paragraph, ranges of comparability for estimated annual heating costs are found in the appropriate appendices accompanying this part.

(8) Placement of the labeled product on the scale shall be proportionate to the lowest and highest annual costs.

(9) Labels must contain the model's energy use in watts as determined in accordance with this part and as indicated on the sample labels in appendix L to this part.

(10) Labels must contain a statement as illustrated in the prototype labels in appendix L and specified as follows:

Cost range based on models with similar capacity.

The cost estimate reflects only the heating cost of this model and does not include other aspects of operation such as water circulation, filtration, or lights.

This label's heating cost estimate is based on continuous heating throughout the year and a national average electricity cost of [____] cents per kWh.

For more information, visit *www.ftc.gov/energy.*

(11) The following statement shall appear on each label as illustrated in the prototype and sample labels in appendix L to this part:

Federal law prohibits removal of this label before consumer purchase.

* * * * *

■ 13. Amend § 305.20 by revising paragraphs (a), (b), (c), (d), (f)(11), and (f)(13) to read as follows:

§ 305.20 Labeling for central air conditioners, heat pumps, and furnaces.

(a) *Layout.* All energy labels for central air conditioners, heat pumps, and furnaces (including boilers) shall use one size, similar colors, and typefaces with consistent positioning of headline, copy, and charts to maintain uniformity for immediate consumer recognition and readability. Trim size dimensions for all labels shall be as follows: width must be between 5¼ inches and 5½ inches (13.34 cm. and 13.97 cm.); length must be between 7⅜ inches (18.78 cm.) and 7⅝ (19.34 cm.). All positioning, spacing, type sizes, and line widths should be similar to and consistent with the prototype and sample labels in appendix L.

(b) *Type style and setting.* The Arial Narrow series typeface or equivalent shall be used exclusively on the label. Specific sizes and faces to be used are indicated on the prototype labels. No hyphenation should be used in setting headline or copy text. Positioning and spacing should follow the prototypes closely. See the prototype labels for specific directions.

(c) *Colors.* The basic colors of all labels covered by this section shall be process yellow or equivalent and process black. The label shall be printed full bleed process yellow. All type and graphics shall be print process black.

(d) *Label type.* The labels must be affixed in the form of an adhesive label, unless otherwise indicated by this section. The adhesion capacity and paper stock should be sufficient to prevent their dislodgment during normal handling throughout the chain of distribution to the retailer or consumer.

* * * * *

(f) * * *

(11) Manufacturers of furnaces (including boilers) shipped with more than one input nozzle to be installed in the field, but no nozzle factory installed, must label such furnaces with the AFUE of the system when it is set up with the nozzle that results in the lowest AFUE rating. See paragraph (f)(13) of this section for furnaces shipped with more than one input nozzle, one of which is factory installed.

* * * * *

(13) Manufacturers of furnaces (including boilers) must label their products with the AFUE rating associated with the furnace's input capacity set by the manufacturer at shipment. The furnace label may also contain a chart, as illustrated in sample label 9B in appendix L to this part, indicating the efficiency rating at up to three additional input capacities offered by the manufacturer. Consistent with paragraph (f)(10)(iii) of this section, labels for furnaces may include the ENERGY STAR logo only if the model qualifies for that program on all input capacities displayed on the label.

* * * * *

■ 14. Amend § 305.22 by revising paragraph (c) to read as follows:

§ 305.22 Energy information disclosures for heating and cooling equipment.

* * * * *

(c) *Furnace labels.* If an installer installs a furnace (including boiler) with an input capacity different from that set by the manufacturer and the manufacturer identifies alternative capacities on the label, the installer must permanently mark the appropriate box on the EnergyGuide label displaying the installed input capacity and the associated AFUE as illustrated in Sample Labels in appendix L to this part.

■ 15. Amend § 305.27 by revising paragraph (a)(1)(i), paragraph (a)(2), and paragraph (b)(1)(i) to read as follows:

§ 305.27 Paper catalogs and websites.

(a) * * *

(1) * * *

(i) *Products required to bear EnergyGuide or Lighting Facts labels.* All websites advertising covered products required to have an EnergyGuide or Lighting Facts label under this part must display, for each model, a recognizable and legible image of the label required for that product by this part. The website may hyperlink to the image of the label using a recognizable thumbnail image or the sample EnergyGuide and Lighting Facts icons depicted in appendix L of this part. The website must hyperlink the image in a way that does not require consumers to save the hyperlinked image to view it.

* * * * *

(2) *Format.* The required website disclosures, whether label image, icon, or text, must appear clearly and conspicuously and in close proximity to the covered product's price on each web page that contains a detailed description of the covered product and its price. The label and hyperlink icon must conform to the prototypes in appendix L, but may be altered in size to accommodate the web page's design, as long as they remain clear and conspicuous to consumers viewing the page. The image or icon required by paragraph (a)(1)(i) of this section must be readily visible to the consumer without requiring any additional scrolling, clicking, or other similar actions.

(b) * * *

(1) * * *

(i) *Products required to bear EnergyGuide or Lighting Facts labels.* All paper catalogs advertising covered products required by this part to bear EnergyGuide or Lighting Facts labels illustrated in appendix L of this part must either display an image of the full label prepared in accordance with this

part, or make a text disclosure as follows:

(A) *Refrigerator, refrigerator-freezer, freezer, and miscellaneous refrigerator product.* The capacity of the model determined in accordance with this part, the estimated annual operating cost determined in accordance with this part, and a disclosure stating ''Your energy cost depends on your utility rates and use. The estimated cost is based on cents per kWh. For more information, visit *www.ftc.gov/energy.*''

(B) *Room air conditioners, portable air conditioners, air cleaners, and water heaters.* The capacity of the model determined in accordance with this part, the estimated annual operating cost determined in accordance with this part, and a disclosure stating ''Your operating costs will depend on your utility rates and use. The estimated operating cost is based on a [electricity, natural gas, propane, or oil] cost of [$ ____per kWh, therm, or gallon]. For more information, visit *www.ftc.gov/energy.*''

(C) *Clothes washers, dishwashers, and clothes dryers.* The capacity of the model determined in accordance with this part, the estimated annual operating cost determined in accordance with this part, and a disclosure stating ''Your energy cost depends on your utility rates and use. The estimated cost is based on [4 washloads a week for dishwashers, or 8 washloads a week for clothes washers, or 5 washloads a week for clothes dryers] and ____cents per kWh for electricity and $____per therm for natural gas. For more information, visit *www.ftc.gov/energy.*''

(D) *General service fluorescent lamps or general service lamps.* All the information concerning that lamp required by § 305.23 of this part to be disclosed on the lamp's package, and, for general service lamps, a disclosure stating ''Your energy cost depends on your utility rates and use. The estimated cost and life is based on 11 cents per kWh and 3 hours of use per day. For more information, visit *www.ftc.gov/energy.*'' For the ''Light Appearance'' disclosure required by § 305.23(b)(3)(iv), the catalog need only disclose the lamp's correlated color temperature in Kelvin (*e.g.,* 2700 K). General service fluorescent lamps or incandescent reflector lamps must also include a capital letter ''E'' printed within a circle and the statement described in § 305.23(g)(1).

(E) *Ceiling fans.* All the information required by § 305.21.

(F) *Televisions.* The estimated annual operating cost determined in accordance with this part and a disclosure stating ''Your energy cost depends on your utility rates and use. The estimated cost is based on 12 cents per kWh and 5 hours of use per day. For more information, visit *www.ftc.gov/energy.*''

(G) *Central air conditioners, heat pumps, and furnaces (including boilers), and pool heaters.* The capacity of the model determined in accordance with this part and the energy efficiency or thermal efficiency ratings determined in accordance with this part on each page that lists the covered product.

(H) *Portable electric spa.* The capacity of the model determined in accordance with this part, the estimated annual operating cost determined in accordance with this part, a disclosure stating ''This label's heating cost estimate is based on continuous heating throughout the year and a national average electricity cost of [____] cents per kWh,'' and a disclosure stating ''Your operating costs will depend on your utility rates and use. The estimated operating cost is based on a [electricity, natural gas, propane, or oil] cost of [$__per kWh, therm, or gallon]. For more information, visit *www.ftc.gov/energy.*''

* * * * *

■ 16. Add Appendix B4 to read as follows:

Appendix B4 to Part 305—Miscellaneous Refrigeration Products Range Information

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy costs (dollars/year)	
	Low	High
Less than 2.5	(*)	(*)
2.6 to 5.0	(*)	(*)
5.1 to 7.5	(*)	(*)
7.6 to 10.0	(*)	(*)
10.1 to 12.5	(*)	(*)
12.6 to 15.0	(*)	(*)
15.1 to 17.5	(*)	(*)
17.6 to 20.0	(*)	(*)
20.1 to 22.5	(*)	(*)
22.6 and over	(*)	(*)

(*) No data.

■ 17. Add Appendix E3 to read as follows:

Appendix E3 to Part 305—Air Cleaners Range Information

Manufacturer's rated room size in square feet	Range of estimated annual energy costs (dollars/year)	
	Low	High
Small (15–154 sq. ft.)	(*)	(*)
Medium (155–235 sq. ft.)	(*)	(*)
Large (236 and greater sq. ft.)	(*)	(*)

(*) No data.

■ 18. Add Appendix F3 and F4 to read as follows:

Appendix F3 to Part 305—Compact Clothes Dryers Range Information

Capacity	Range of estimated annual energy costs (dollars/year)	
	Low	High
Compact	(*)	(*)

(*) No data.

Appendix F4 to Part 305—Standard Clothes Dryers Range Information

Capacity	Range of estimated annual energy costs (dollars/year)	
	Low	High
Standard	(*)	(*)

(*) No data.

■ 19. Add Appendix J3 to read as follows:

Appendix J3 to Part 305—Portable Electric Spas Range Information

Manufacturer's rated capacity in gallons	Range of estimated annual heating costs (dollars/year)	
	Low	High
200 sq. ft. or less	(*)	(*)
201–400 sq. ft	(*)	(*)
401–600 sq. ft	(*)	(*)
600 sq. ft. or larger	(*)	(*)

(*) No data.

■ 20. Revise Appendix K1 to read as follows:

Appendix K1 to Part 305—Representative Average Unit Energy Costs for Refrigerators, Refrigerator-Freezers, Freezers, Miscellaneous Refrigerator Products, Clothes Washers, Clothes Dryers, Dishwashers, Air Cleaners, Portable Electric Spas, and Water Heater Labels

This Table contains the representative unit energy costs that must be utilized to calculate estimated annual energy cost disclosures required under this Part for refrigerators, refrigerator-freezers,

freezers, miscellaneous refrigerator products, clothes washers, clothes dryers, dishwashers, air cleaners, portable electric spas, and water heaters. This Table is based on information published by the U.S. Department of Energy in 2022.

Type of energy	In commonly used terms	As required by DOE test procedure
Electricity	¢14/kWh [1] [2]	$.1400/kWh.
Natural Gas	$1.21/therm,[3] $12.6/MCF [5] [6]	$0.00001209/Btu.[4]
No. 2 Heating Oil	$3.45/gallon [7]	$0.00002511/Btu.
Propane	$2.23/gallon [8]	$0.00002446/Btu.
Kerosene	$4.01/gallon [9]	$0.00002973/Btu.

[1] kWh stands for kiloWatt hour.
[2] 1 kWh = 3,412 Btu.
[3] 1 therm = 100,000 Btu. Natural gas prices include taxes.
[4] Btu stands for British thermal unit.
[5] MCF stands for 1,000 cubic feet.
[6] For the purposes of this table, 1 cubic foot of natural gas has an energy equivalence of 1,039 Btu.
[7] For the purposes of this table, one gallon of No. 2 heating oil has an energy equivalence of 138,500 Btu.
[8] For the purposes of this table, one gallon of liquid propane has an energy equivalence of 91,333 Btu.
[9] For the purposes of this table, one gallon of kerosene has an energy equivalence of 135,000 Btu.

■ 21. Amend Appendix L by adding samples labels 18, 19, and 20 to read as follows:

Appendix L to Part 305—Sample Labels

* * * * *

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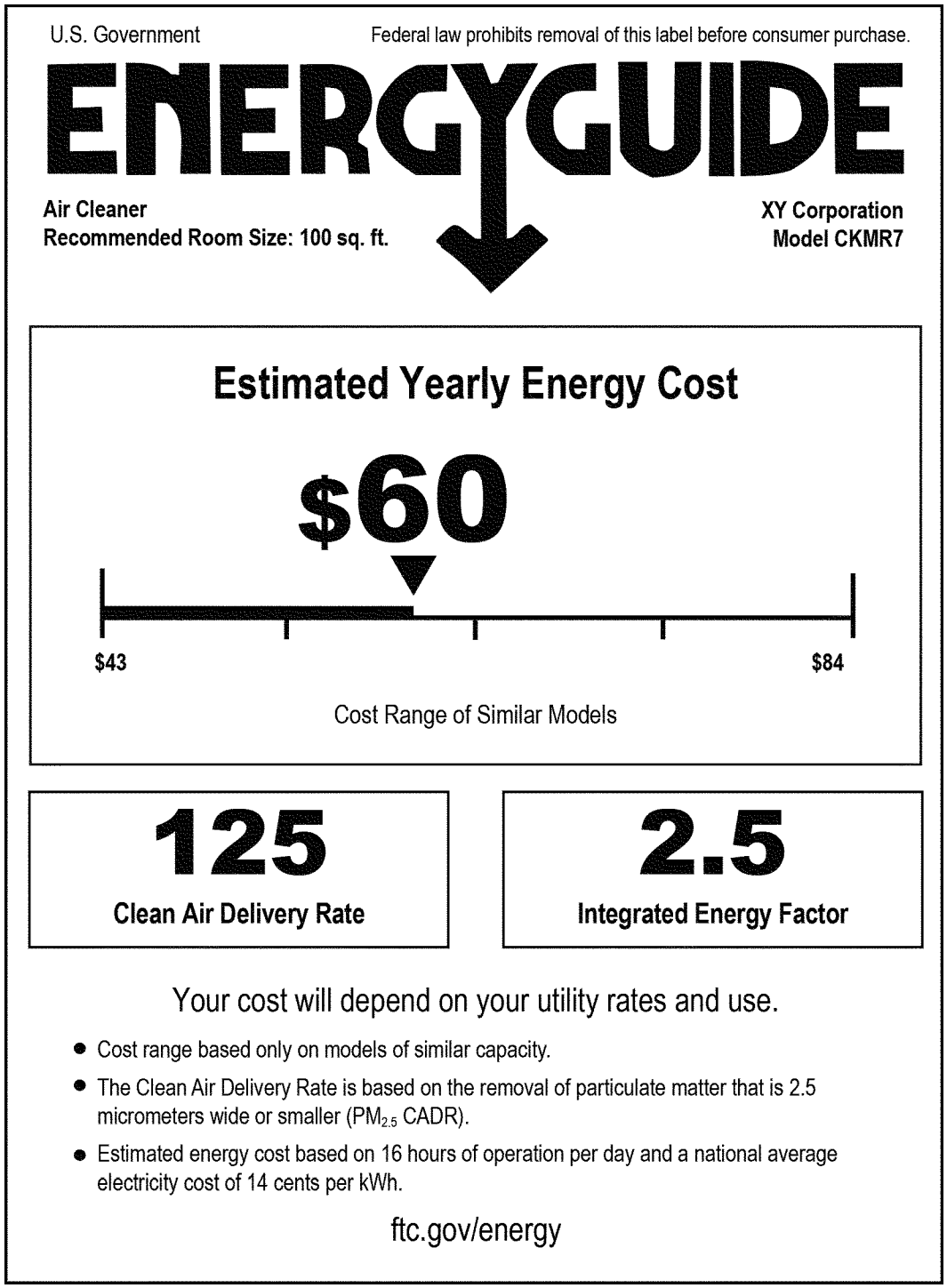
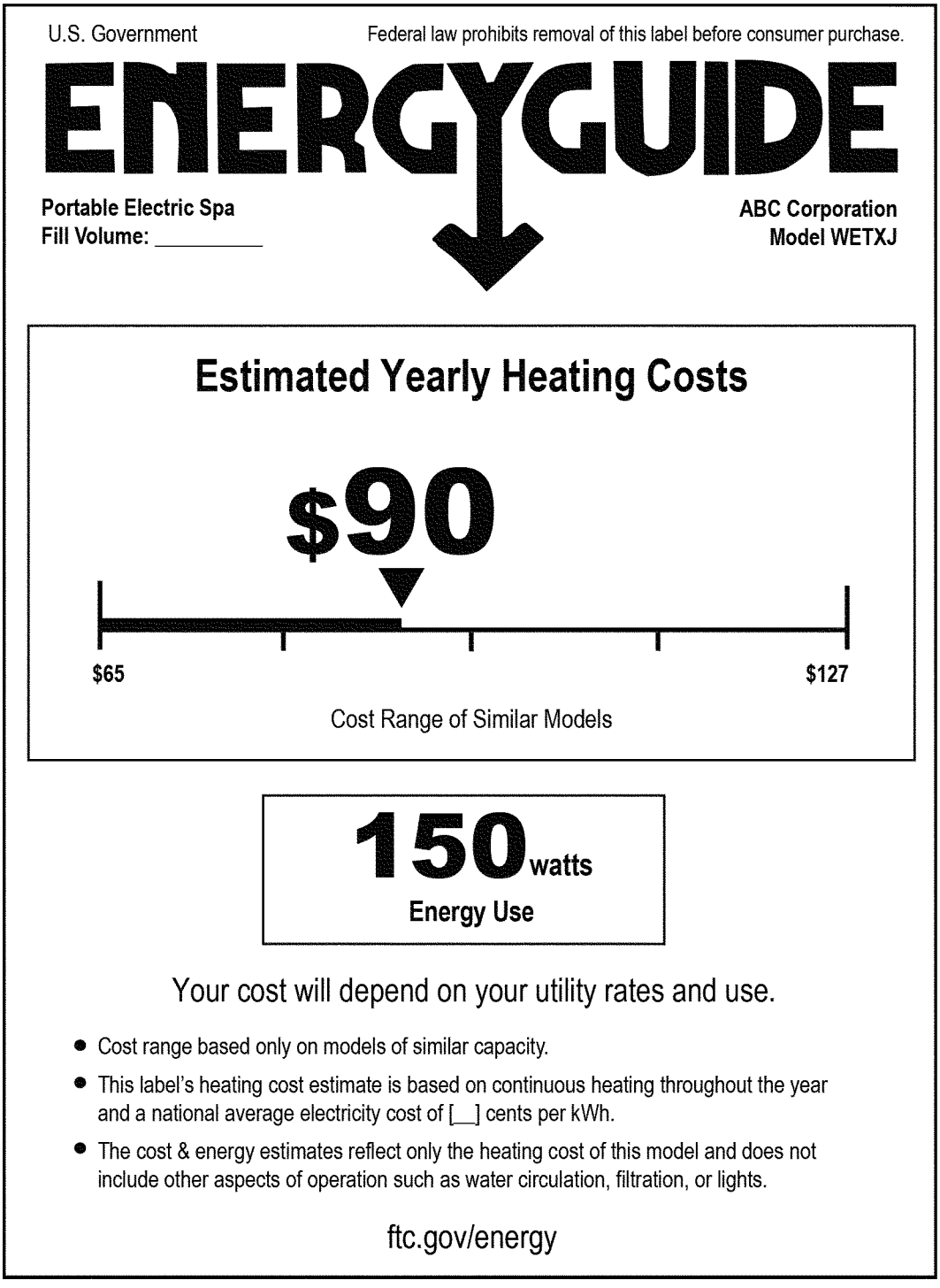
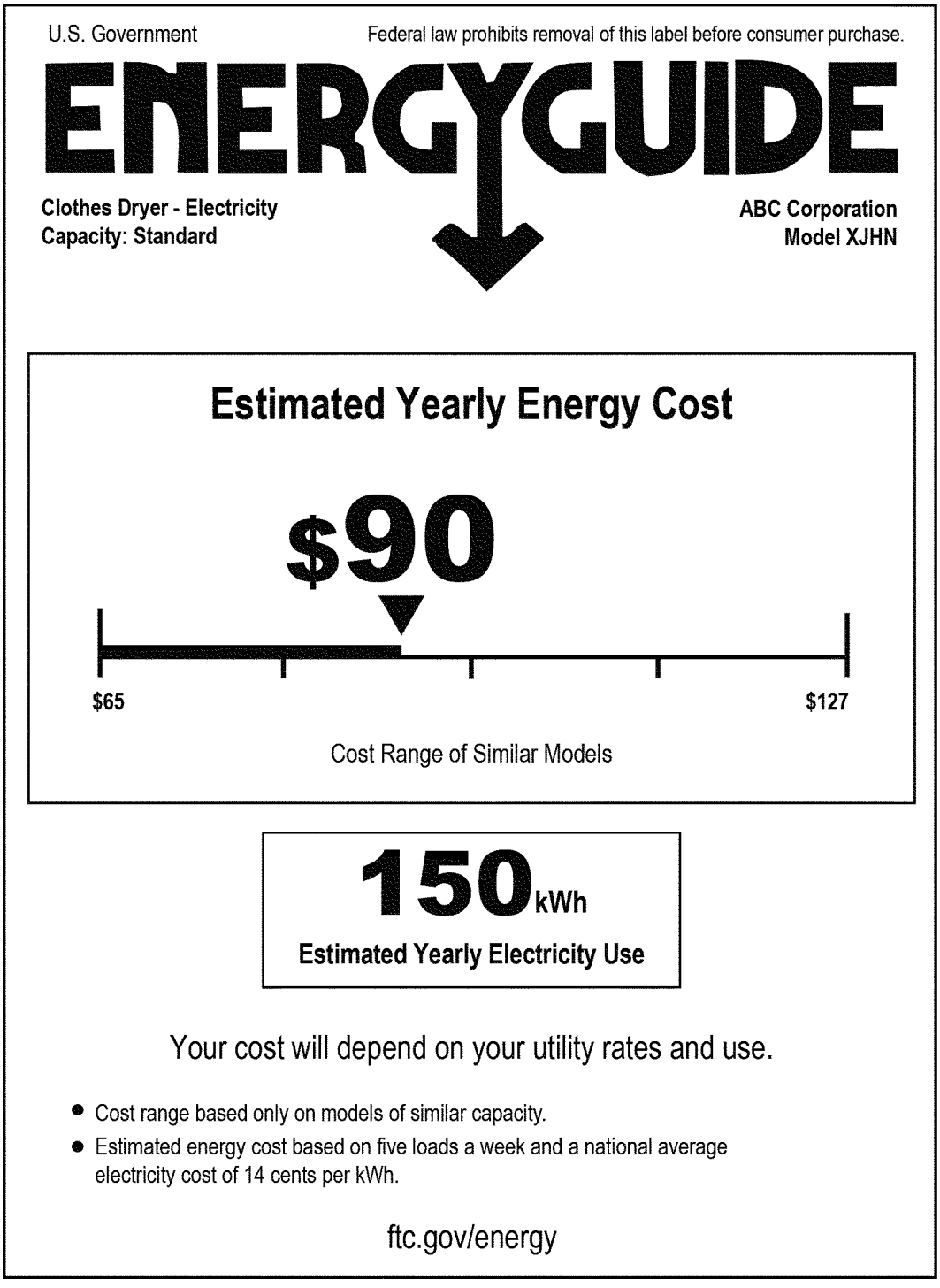
Sample Label 18 – Air Cleaner



Sample Label 19 - Portable Electric Spa



Sample Label 20 - Clothes Dryer



By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2024–01601 Filed 2–1–24; 8:45 am]

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